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BIOPHEN®
ARIXTRA® CONTROL PLASMA
Ref 224001

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

For in vitro diagnostic use only

Last revision: 06/11/2014

ENGLISH

INTENDED USE:
Biophen® Arixtra® Control Kit is a set of control plasmas supplemented with Arixtra® at 2 different levels, and lyophilized. They are titrated and optimised for anti-Xa chromogenic assays, such as BIOPHEN® HEPARIN 3 and 6 (Ref. 221003/221006) and BIOPHEN® Heparin LRT (Ref. 221011/221013) assays.

CLINICAL INTEREST:
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. These control plasmas are used for the quality control of Arixtra® with anti-Xa chromogenic assay.

REAGENTS:
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, freeze-dried, with an Arixtra® concentration in the range 0.30 – 0.50 µg/mL. 6 vials of 1 mL

C2: ***Control 2:***
Human plasma, freeze-dried, with an Arixtra® concentration in the range 1.05 – 1.35 µg/mL. 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, and stabilizers.
- Each human plasma unit is from healthy donors. Each plasma 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.

REAGENT REQUIRED BUT NOT PROVIDED:
Reagents:
BIOPHEN® Heparin 3 or 6 (ref. 221003/221006) or equivalent.
BIOPHEN® Heparin LRT (Ref. 221011/221013)
BIOPHEN® Arixtra® Calibrator (ref. 222501) or equivalent.
Distilled water

Materials:
Spectrophotometer or automated analysers for chromogenic assays.
Calibrated pipettes.

TRACEABILITY:
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.

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 controls 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).
- Do not freeze

CAUTIONS:
- Vials are closed under vacuum. Remove carefully the stopper, in order to avoid any loss of powder when opening the vials.
- In order to ensure stability, reagents must be closed with their original screw cap following each use, or stored closed in the micro plastic containers in which the plasma could be aliquoted (depending on the protocol and the instrument used).
- Reagents must be handled with care, in order to avoid any contamination during use.
- It is recommended to homogenize each plasma before use, in order to have a good reproducibility (at all 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, e.g. by using chimneys, when available.
- The disposal of waste materials will be carried out according to current local regulations.

PROCEDURE:
Refer to the packaging insert of the anti-Xa reagent used.

QUALITY CONTROL:
If controls are out of the acceptance range, the test series must be invalidated, and the assay should be rerun. Check all the components of the test system, before repeating the assay.
If used with anti Xa assays from other manufacturers, measured values can vary according to the assay reactivity and its standardization: each laboratory must then determine and validate the acceptance ranges in its specific test conditions.

PERFORMANCE:
The Arixtra® concentrations of controls may vary from lot to lot, but they are exactly indicated, for each lot, on the flyer provided.
The following Arixtra® concentrations are provided for information only:

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

BIOPHEN Arixtra® Control (lot 91801, tested using Biophen Heparin with 1 series water bath, 1 series ACL7000, and 7 series STAR for inter assay)

CARACTERISTICS:
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, especially when used with anti-Xa methods. The results are guaranteed and optimised for being used with Biophen® Heparin 3 and 6 (ref. 221003/221006) and BIOPHEN® Heparin LRT (Ref. 221011/221013) assays.
The target values for controls have been made determined using the anti-Xa assays (Biophen® Heparin kits).

LIMITATIONS:
- As all lyophilized plasmas, control plasmas are more or less cloudy after reconstitution. This is due essentially to lipids that, after lyophilisation, become less soluble and can form a small 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:
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.
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.