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|-------------------------------|----------------|---------------------------------|-----|
| REF | 5090012 | Technoview Arixtra CON L | ENG |
| REF | 5090014 | Technoview Arixtra CON H | |
| 3015212RUO Rev.001 15/06/2021 | | | RUO |



Biological risk



Control

Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH, Brunner Str. 67 - 1230 Vienna, Austria
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 Arixtra is a registered trademark of GlaxoSmithKline Company.

Technoview Arixtra Controls - English

INTENDED USE

Technoview Arixtra CON L and CON H are plasmas with differernt concentrations of Arixtra (low and high) to be used for quality control measurements of Arixtra. They are optimized using Technochrom anti-Xa assay.

SUMMARY

Fondaparinux sodium (Arixtra) is an anticoagulant, used as an alternative therapy to Heparin or low molecular weight Heparin (LMWH), when these latter drugs are contraindicated.

REAGENTS

The REF 5090012 Technoview Arixtra CON L contains:

| Reagent | Description |
|----------------|---|
| 6 x 1 mL CON L | Human plasma, lyophilized, ~0.4 µg/mL Arixtra |

Please consult the lot specific batch table provided with the controls for the exact concentrations in µg/mL of each calibrator.

The REF 5090014 Technoview Arixtra CON H contains:

| Reagent | Description |
|----------------|---|
| 6 x 1 mL CON H | Human plasma, lyophilized, ~1.2 µg/mL Arixtra |

Please consult the lot specific batch table provided with the controls for the exact concentrations in µg/mL of each calibrator.

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes (1000 µL)
- Laboratory timer
- REF 5340250 Technochrom anti-Xa
- REF 5090010 Technoview Arixtra CAL

Warning and precautions

- RUO for research use only.
- This kit is intended for use by personnel trained in laboratory procedures and universal precautions for the use of chemicals and potentially biohazardous substances must be applied.
- All human blood or plasma products as well as test samples must be considered as potentially infectious. They have to be handled with appropriate care and in strict observance of safety regulations. The rules pertaining to disposal are the same as applied to disposing hospital waste.
- Calibrators and control plasmas are made from human blood and any individual plasma involved in the procedure is tested HbsAg, HIV 1/2 Ab and HCV-Ab-negative. However, all human blood products should be handled as potentially infectious material.
- Get a Material Safety Data Sheet for this product from www.technoclone.com.

Stability and storage

The expiry date printed on the labels is only applicable to storage of the unopened containers at 2...8 °C.

Stability opened/ in use:

| Reagent | 18...25 °C (open vial) | 2...8 °C (closed vial) | -20 °C |
|--------------------------|------------------------|------------------------|---------|
| Technoview Arixtra CON L | 48 hours | 7 days | 1 month |
| Technoview Arixtra CON H | 48 hours | 7 days | 1 month |

Control material can only be frozen once, in its original vial.

TEST PROCEDURE

Preparation of controls

Before starting the test, all the required components are to be brought to room temperature.

When reconstituting plasmas, mixing reagents or buffers avoid foaming.

- *Technoview Arixtra CON L*: Reconstitute each control vial with 1.0 mL of distilled water. Allow the reconstituted material to stand at room temperature for 30 minutes followed by swirling of the vial before use.
- *Technoview Arixtra CON H*: Reconstitute each control vial with 1.0 mL of distilled water. Allow the reconstituted material to stand at room temperature for 30 minutes followed by swirling of the vial before use.

Performance of the test

The Technoview Arixtra CAL is always used in combination with the Technoview Arixtra CON L and Technoview Arixtra CON H and the Technochrom anti-Xa kit.

The Arixtra concentration of the controls may vary from one lot to another but is clearly indicated in the lot specific batch table provided in the control box.

Technoclone provides instrument specific application sheets, which contain analyser / assay specific handling and performance information.

STANDARDISATION

The Technoview Arixtra controls are directly traceable to an internal reference standard.

LITERATURE

Please contact Technoclone www.technoclone.com or your local distributor.

EDITORIAL NOTE

This document is available in several languages. The translations have been done using the master document in English. In the event of doubts or discrepancies, the wording in the master document in English shall take precedence.



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|--|------------------------------|--|--------------------------|
| | Manufacturer | | Lot |
| | Storage temperature | | Research Use Only |
| | Expiry date | | Catalogue number |
| | Consult instructions for use | | Global Trade Item Number |