

# BIOPHEN™ Arixtra® Calibrator

REF 222501-RUO

CAL1 CAL2 CAL3 CAL4 3 vials x 1 mL

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

English, last revision: 04-2024

## INTENDED USE:

For calibration of Arixtra® (Fondaparinux) assays, using a quantitative manual or automated method.

**This kit is for research use only and must not be used for patient diagnosis or treatment.**

## SUMMARY AND EXPLANATION:

### Technical:

These calibrators are used to establish the calibration curve of Arixtra® in plasma by anti-Xa chromogenic assays (BIOPHEN™ Heparin 3 and 6 and BIOPHEN™ Heparin LRT).

## REAGENTS:

- CAL1** Lyophilized human plasma without Arixtra®.
- CAL2** Lyophilized human plasma containing approximately 0.5 µg/mL of Arixtra®.
- CAL3** Lyophilized human plasma containing approximately 1.0 µg/mL of Arixtra®.
- CAL4** Lyophilized human plasma containing approximately 1.5 µg/mL of Arixtra®.

Calibrator plasmas contain stabilizing agents.

The calibrator concentrations may vary slightly from one batch to another. For the assay, see the exact values indicated on the flyer provided with the kit used.

The product is classified as non-hazardous and is not subject to labeling according to EC Regulation No. 1272/2008 [CLP].

## WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human origin. Whenever human plasma is required for the preparation of these reagents, approved methods are used to test the plasma for the antibodies to HIV 1, HIV 2 and HCV, and for hepatitis B surface antigen, and results are found to be negative. However, no test method can offer complete assurance that infectious agents are absent. Therefore, users of reagents of these types must exercise extreme care in full compliance with safety precautions in the manipulation of these biological materials as if they were infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- This device of *in vitro* use is intended for professional use in the laboratory.

## REAGENT PREPARATION:

Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

**CAL1 CAL2 CAL3 CAL4** Reconstitute the contents of each vial with exactly 1 mL of distilled water. Shake vigorously until complete dissolution while avoiding formation of foam and load it directly on the analyzer following Application Guide instruction. For manual method, allow to stabilize for 10 minutes at room temperature (18-25°C), homogenize before use.

This plasmatic reagent can be more or less turbid after reconstitution. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit. If necessary, let each vial stabilize 10 minutes at room temperature and shake before use.

## STORAGE AND STABILITY:

Unopened reagents should be stored at 2-8°C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

**CAL1 CAL2 CAL3 CAL4** Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- 7 days at 2-8°C.
- 48 hours at room temperature (18-25°C).
- 60 days frozen at -20°C or less\*
- **Stability on board of the analyzer: see the specific Application Guide.**

\*Thaw only once, as rapidly as possible at 37°C and use immediately.

## REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Laboratory material.

## TRACEABILITY:

Calibrators are traceable to US Pharmacopoeia (USP) Reference Standard for Fondaparinux sodium.

Certificate of traceability and uncertainty is available on the HYPHEN BioMed website:

Uncertainty			
<b>CAL1</b>	± 0.00 µg/mL	<b>CAL3</b>	± 0.04 µg/mL
<b>CAL2</b>	± 0.02 µg/mL	<b>CAL4</b>	± 0.07 µg/mL

## QUALITY CONTROL:

For calibration of Arixtra® assays by anti-Xa chromogenic methods, with BIOPHEN™ Heparin 3 and 6 (221003-RUO/221006-RUO) and BIOPHEN™ Heparin LRT (221011-RUO/221013-RUO/221015-RUO) kits.

The target values are determined from multi-reagent and multi-instrument tests. The use of quality controls serves to validate method compliance, along with between-series assay homogeneity for a given batch of reagents. Include the quality controls with each series, as per good laboratory practice, in order to validate the test.

A new calibration curve should be established, preferably for each test series, and at least for each new reagent batch, or after analyzer maintenance, or when the measured quality control values fall outside the acceptance range for the method.

## LIMITATIONS:

- If the calibrators are used under measurement conditions other than those validated by HYPHEN BioMed, the test results may vary. The laboratory is responsible for validating the use of these calibrators in its own analytical system.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.

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

For customer support or Application Guides, please contact your local provider or distributor (see www.hyphen-biomed.com).

Changes compared to the previous version.

The following symbols may appear on the product labeling:

<b>REF</b>	Catalogue number	<b>LOT</b>	Batch code	<b>RUO</b>	Product for <i>in-vitro</i> research use, only
<b>Rx</b>	Numerical < x> identification of reagent		See instructions for use	<b>WHO STD</b>	WHO standard code
	Temperature limitation		Manufacturer		Use by
	Biological risks	→	Reconstitution volume	<b>CONTENTS</b>	Contents
<b>Cx</b>	Numerical < x> identification of control		See instructions in Method Application guide	<b>CONTAINS</b>	Contains
<b>EXP</b>	Expiration date		Contains sufficient for <n> tests	<b>UNIT</b>	Measurement unit
<b>TARGET VALUE</b>	Target Value		Keep away from sunlight and heat	<b>CALx</b>	Numerical < x> identification of calibrator
	Contains biological material of animal origin		Contains human blood or plasma derivatives	<b>DANGER</b>	Danger
<b>WARNING</b>	Warning	<b>ACCEPTANCE RANGE</b>	Acceptance range		