HYPHEN BioMed
www.hyphen-biomed.com
155, rue d'Eragny
95000 NEUVILLE SUR OISE
FRANCE
Tel. : +33 (0)1 34 40 65 10
Fax : +33 (0)1 34 48 72 36
info@hyphen-biomed.com

ARGATROBAN®
PLASMA CALIBRATOR
Ref SC030K-RUO

Calibration plasmas for the assay of Argatroban® with anti-IIa method

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

Last revision: 01/12/2014

INTENDED USE:

Argatroban® Plasma Calibrator is a set of calibration plasmas for Argatroban® (also called Argatra®, Arganova®, or Novastan®), measurements, titrated and optimised using the anti-IIa clotting assay **HEMOCLOT THROMBIN INHIBITORS (CK002K-RUO/CK002L-RUO).**
Argatroban® Plasma Calibrator allows calibrating the assays of Argatroban® using clotting anti-IIa methods, especially when the HEMOCLOT Thrombin Inhibitors kit is used, with the low range protocol. **This kit is for research use only and should not be used for patient diagnosis or treatment.**

REAGENTS SUPPLIED:

20 vials (4 sets of 5 vials) of 1 ml human plasma supplemented with different concentrations of Argatroban® (4 vials for each concentration).

CAL 1: ***Calibrator 1:*** 1mL 4 vials.
Human plasma, freeze-dried, without any addition of Argatroban® (level 1 at 0 µg/ml) (to be restored with 1 mL distilled water).

CAL 2: ***Calibrator 2:*** 1mL 4 vials.
Human plasma, freeze-dried, supplemented with Argatroban® (level 2 at about 0.5 µg/ml) (to be restored with 1 mL distilled water).

CAL 3: ***Calibrator 3:*** 1mL 4 vials.
Human plasma, freeze-dried, supplemented with Argatroban® (level 3 at about 1.0 µg/ml) (to be restored with 1 mL distilled water).

CAL4 : ***Calibrator 4:*** 1mL 4 vials.
Human plasma, freeze-dried, supplemented with Argatroban® (level 4 at about 1.50 µg/ml) (to be restored with 1 mL distilled water).

CAL5 : ***Calibrator 5:*** 1mL 4 vials.
Human plasma, freeze-dried, supplemented with Argatroban® (level 5 at about 2.00 µg/ml) (to be restored with 1 mL distilled water).

The exact concentration of Argatroban® in each vial is indicated on the flyer provided in each kit. The calibration curve covers the range from 0 to about 2.0 µg/ml.

Note:
- Calibrator plasmas contain an antibiotic as preservative (ciprofloxacin).
- 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 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.
  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 Argatroban® Plasma Calibrator kit contains 4 sets of 5 vials supplemented with increasing concentrations of Argatroban®.
The following values, obtained for one lot of Argatroban® Plasma Calibrator (on water bath, ACL and/or STAR), are provided as an example only.

Calibrator	Argatroban® concentration (µg/ml)	Intra assay		Inter assay	
		N	SD	N	SD
CAL 1	0	10	na	9	na
CAL 2	0.60	10	0.04	9	0.05
CAL 3	1.15	10	0.06	9	0.08
CAL 4	1.55	10	0.06	9	0.08
CAL 5	2.02	10	0.08	9	0.15

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 Argatroban® diluted into a normal human plasma pool.
The concentrations have been optimised and are guaranteed with the HEMOCLOT Thrombin Inhibitors kit.
The calibration curve covers the range from 0 to about 2.0 µg/ml.

PERFORMANCE CHARACTERISTICS:

Argatroban® Plasma Calibrators allow establishing the calibration curve for the measurement of Argatroban® in plasma, especially with Anti-IIa methods. Using the **HEMOCLOT Thrombin Inhibitors (ref. CK002K-RUO or CK002L-RUO)** kit, Argatroban® is measured with the **low range protocol**, and the assay is linear up to about 2 µg/ml using the manual method or the STA-R instrument.
The **Argatroban® Control Plasma (ref SC035K-RUO)** can be used in order to obtain an homogeneous quality control system.
The HEMOCLOT Thrombin Inhibitors anti-IIa method, used according to the **low range protocol**, for the measurement of Argatroban® concentrations in plasma, offers a sensitivity threshold of about 0.05 µg/ml.

CAUTIONS:

- Like all lyophilised plasmas, the calibration plasmas from the Argatroban® Plasma 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.
- **The results obtained should be for research purposes only and not used for patient diagnosis or treatment.**