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ARGATROBAN® CONTROL PLASMA
Ref SC035K

CE

Human plasmas at two levels of Argatroban® for the quality control of Argatroban® measurements with anti-IIa methods

For in vitro diagnostic use only

Not for Sale in the US

Last revision: 01/12/2014

ENGLISH

INTENDED USE:

Argatroban® Control Plasma Kit is a set of control plasmas for the quality control of Argatroban® (also called Argatra®, Arganova® or Novastan®) measurements, using anti-IIa clotting assays. This kit is optimised for being used with the **HEMOCLOT THROMBIN INHIBITORS assay** (low range protocol)**(#CK002K/L**).

SUMMARY AND EXPLANATION:

Argatroban® can be used as an anticoagulant for curative indications, mainly in emergency situations. Measuring the Argatroban® concentration in patients' plasma allows monitoring the therapy and adjusting drug dosage. These control plasmas are used for the quality control of clotting assays proposed for measuring Argatroban® concentrations in plasma.

REAGENTS SUPPLIED:

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

C1 : ***Control 1***
Human plasma, freeze-dried, supplemented with Argatroban® (level 1 at about 0.65 µg/mL) (to be restored with 1 mL distilled water). 6 vials of 1 mL

C2 : ***Control 2:***
Human plasma, freeze-dried, supplemented with Argatroban® (level 2 at about 1.25 µg/mL) (to be restored with 1 mL distilled water). 6 vials of 1 mL

The Argatroban® 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 (ciprofloxacin).
- 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 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:

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

CONCENTRATION:

Each Argatroban® Control Plasma kit contains 2 sets of 6 vials with 2 different concentrations of Argatroban® (low and high). The exact concentrations may present variations from lot to lot, but they are exactly determined for each lot.
The Argatroban® concentrations and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

The following example shows the Argatroban® concentrations indicated for one lot of Argatroban® Control Plasma (obtained on water bath, ACL and/or STAR):

Argatroban® Control	Argatroban® (µg/ml)	Acceptance range (µg/ml)	Intra assay		Inter assay	
			N	SD	N	SD
Level 1	0.76	0.61-0.91	10	0.04	9	0.05
Level 2	1.25	1.05-1.45	10	0.08	9	0.08

The control **C1** has usually a concentration of 0.65 ± 0.15 µg/mL.

The control **C2** has usually a concentration of 1.25 ± 0.20 µg/mL.

QUALITY CONTROL:

Argatroban® Control Plasmas (level 1 and 2) are proposed for the quality control of calibration curves established for the measurements of Argatroban® 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 Argatroban® control kit, which contains plasmas at 2 different Argatroban® concentrations, can be used in association with **Argatroban® Plasma Calibrator (#SC030K)** for testing Argatroban® in plasma, more especially with the **HEMOCLOT Thrombin Inhibitors kit (#CK002K/L).**

PERFORMANCE CHARACTERISTICS:

Argatroban® Control plasmas allow validating the calibration curve for the measurements of Argatroban® in plasma, especially with Anti-IIa methods. The results are guaranteed and optimised for being used with the **Hemoclot Thrombin Inhibitors (ref. CK002K/L)** assay (**low range protocol**).

The results obtained could present little variation, when these controls are used with other kits according to the assay reactivity and its standardization. These controls can nevertheless be used with different kits for quality control and testing run to run variability, but the acceptable values must be determined by each laboratory.

The Hemoclot Thrombin Inhibitors anti-IIa method, used for the measurement of Argatroban® in plasma, offers a sensitivity threshold of about 0.05 µg/mL.

CAUTIONS:

- Like all lyophilised plasmas, the control plasmas from the Argatroban® 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.

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