Argatroban Plasma Calibrator

CE

IVD

REF SC030K

CAL1 CAL2 CAL3 CAL4 CAL5 4 x 1 mL

Calibration human plasmas for Argatroban measurements with anti-IIa method.

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

English, Last revision: 09-2017

INTENDED USE:

The Argatroban Plasma Calibrator kit consists of lyophilized human plasmas overloaded with Argatroban, for the calibration of the Argatroban assay in human plasmas. It is titrated and optimized for the clotting assay of Argatroban (Low range) and more especially for the HEMOCLOT Thrombin Inhibitors kit (CK002K/CK002L).

SUMMARY AND EXPLANATION:

Argatroban is a synthetic Direct Thrombin Inhibitor, which can be used as an anticoagulant for curative indications, mainly in emergency situations. Measuring the Argatroban concentration in patients' plasma can be used for monitoring the therapy and adjusting drug dosage. Argatroban Plasma Calibrators are used in order to establish the calibration curve for Argatroban clotting assays in plasma.

REAGENTS:

CAL1 **Calibrator 1:** Lyophilized human plasma without Argatroban (0 µg/mL) (level 1).
4 vials of 1 mL.
CAL2 **Calibrator 2:** Lyophilized human plasma containing a titrated quantity of Argatroban of approximately 0.50 µg/mL (level 2).
4 vials of 1 mL.
CAL3 **Calibrator 3:** Lyophilized human plasma containing a titrated quantity of Argatroban of approximately 1.00 µg/mL (level 3).
4 vials of 1 mL.
CAL4 **Calibrator 4:** Lyophilized human plasma containing a titrated quantity of Argatroban of approximately 1.50 µg/mL (level 4).
4 vials of 1 mL.
CAL5 **Calibrator 5:** Lyophilized human plasma containing a titrated quantity of Argatroban of approximately 2.00 µg/mL (level 5).
4 vials of 1 mL.

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

WARNINGS AND PRECAUTIONS:

- Calibrator plasmas contain stabilizing agents.
- Each pouch of human plasma used for kit preparation was obtained from healthy donors. Each plasma used was screened for the presence of the HBs antigen, of anti-HIV1, anti-HIV2 and anti-HCV antibodies, using approved methods, and found to be negative. Nevertheless, no tests can totally exclude the presence of infectious agents. For this reason, every precaution required for the use of potentially infectious products should be taken when handling and disposing of plasma.
- Waste should be disposed of in accordance with applicable local regulations.
- Handle the reagents with care to avoid contamination during use. If possible, avoid reagent evaporation during use by limiting the liquid-air exchange surface. Evaporation reduces the reagent's stability in the analyzer.
- To ensure reagent stability, seal the vials after use with their respective caps, or close the plastic micro-containers into which the plasmas may have been transferred, depending on the protocol used.
- Aging studies, conducted over a 3-week period at 30°C, show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- For *in vitro* diagnostic use.

REAGENT PREPARATION AND STABILITY:

The reagents are lyophilized under vacuum in their vials. To avoid any product loss when opening the vial of lyophilized reagents, gently remove the freeze-drying stopper.

CAL1 CAL2 CAL3 CAL4 CAL5
Reconstitute the contents of each vial with exactly **1 mL distilled water**, shake vigorously until fully dissolved.
Allow to stabilize for 30 min. at room temperature (18-25°C), shaking occasionally.
Homogenize prior to use.
Reagent stability after reconstitution, free from any contamination or evaporation, and stored in the original vial, is of:

- **7 days** at 2-8°C.
- **48 hours** at room temperature (18-25°C).
- **Do not freeze.**

STORAGE CONDITIONS:

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.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:

- Distilled water.

Materials:

- Calibrated pipettes.

TRACEABILITY:

The value assignment of calibrators is related to the corresponding Internal Standard for Argatroban, initially standardized against a reference preparation of Argatroban.

PROPERTIES:

The Argatroban Plasma Calibrator kit is used to establish a calibration curve to measure Argatroban in plasma by anti-IIa methods, such as those provided by HEMOCLOT Thrombin Inhibitors (CK002K/CK002L) kit (low range protocol).
The calibrator target values are determined from 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 defined, 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 acceptable range for the method.

LIMITATIONS:

- Like all lyophilized plasmas, calibration plasmas are more or less turbid once resuspended. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit.
- Any plasma displaying a coagulum or showing signs of bacterial or fungal contamination must be rejected.
- 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.

REFERENCES:

1. Matsuo T, "Argatroban: Antithrombotic therapy in Clinical Practice", Kobe research projects on thrombosis and Haemostasis. 2007.
2. Satellite symposium of the XXIst ISTH congress, "Landmarks in anti-thrombin drug development: the argatroban story", Mitsubishi Tanabe Pharma Corporation. 2007.
3. Koster *et al,* "Anticoagulation with Argatroban in patients with heparin-induced thrombocytopenia antibodies after cardiovascular surgery with cardiopulmonary bypass: first results from the ARG-E03 trial", J. of Thoracic and Cardiovasc. Surgery. 2006.
4. Reddy B. *et al,* "Argatroban anticoagulation in patients with Heparin-Induced Thrombocytopenia requiring renal replacement therapy", Ann Pharmacother, 2005; 39:1601-5.
5. Fareed J. Jeske P. "Small-molecule direct antithrombins: argatroban", Best Practice and Research Clinical Haematology. 2004.
6. Lewis *et al,* "Argatroban anticoagulation in patients with Heparin-Induced Thrombocytopenia", Arch Intern Med. 2003.
7. Fenyvesi T. *et al,* "Influence of lepirudin, argatroban, and melagatran, on Prothrombin Time and additional effect of oral anticoagulation", Clinical chemistry, 2002.

SYMBOLS:

Symbols used and signs listed in the ISO 15223-1 standard, see Symbol definitions document.