



Argatroban Control Plasma

REF SC035K

C1 C2 6 x 1 mL

Human plasmas at 2 levels of Argatroban for the quality control of Argatroban assay by anti-IIa method.

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INTENDED USE:

The Argatroban Control Plasma kit consists of lyophilized human plasmas, overloaded with Argatroban at two concentrations, for the quality control of Argatroban assay. It is titrated and optimized for the clotting assay of Argatroban and more especially for 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. These control plasmas are used for the quality control of clotting assays proposed for measuring Argatroban concentrations in plasma (CK002K/CK002L).

REAGENTS:

C1 Control 1: Lyophilized human plasma containing a titrated quantity of Argatroban of approximately 0.65 µg/mL (level 1).

6 vials of 1 mL.

C2 Control 2: Lyophilized human plasma containing a titrated quantity of Argatroban of approximately 1.25 µg/mL (level 2).

6 vials of 1 mL.

The control 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:

- Control 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.

C1 and C2 Control 1 and 2

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).

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 controls is related to the corresponding Internal Standard for Argatroban, initially standardized against a reference preparation of Argatroban.

PROPERTIES:

The Argatroban Control Plasma kit is used for the quality control of Argatroban assays in plasma with anti-IIa method, such as those provided by the HEMOCLOT Thrombin Inhibitors (CK002K/CK002L).

The control 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.

If the controls fall outside of the acceptable range, the series of assays must be invalidated and the analyses repeated. Check all system parameters before repeating the series.

LIMITATIONS:

- Like all lyophilized plasmas, control 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 controls 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 controls in its own analytical system.

REFERENCES:

1. Matsuo T, "Argatroban: Antithrombotic therapy in Clinical Practice", 2007, Kobe research projects on thrombosis and Haemostasis.
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.
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.