Argatroban Control Plasma

**INTENDED USE:**
The Argatroban Control Plasma kit consists of lyophilised 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 patient’s 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).
- **C2** Control 2: Lyophilized human plasma containing a titrated quantity of Argatroban of approximately 1.25 µg/mL (level 2).

**WARNINGS AND PRECAUTIONS:**
- Control plasmas contain stabilizing agents.
- Each pouch ofhuman 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.

**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.

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**REFERENCES:**

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