Plasma Hirudin Control

REF SC025K

C1 C2 3 x 1 mL

IVD

Human plasmas at 2 levels for the quality control of Hirudin clotting assay.

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INTENDED USE:

The Plasma Hirudin Control kit consists of lyophilised human plasmas, overloaded with Hirudin (Lepirudin) at two concentrations, for the quality control of Hirudin assay. It is titrated and optimized for the clotting assay of Hirudin and more especially for HEMOCLOT Thrombin Inhibitors kit (CK002K/CK002L).

SUMMARY AND EXPLANATION:

Hirudin can be used as an anticoagulant for curative indications, mainly in emergency situations. Measuring the Hirudin 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 Hirudin concentrations in plasma (CK002K/CK002L).

REAGENTS:

C1 **Control 1:** Lyophilized human plasma containing a titrated quantity of Hirudin of approximately 1.00 µg/mL (level 1, low concentration).
3 vials of 1 mL.
C2 **Control 2:** Lyophilized human plasma containing a titrated quantity of Hirudin of approximately 2.00 µg/mL (level 2, high concentration).
3 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:

- **48 hours** at 2-8°C.
- **24 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 Hirudin, initially standardized against a pharmaceutical reference preparation of Hirudin (Lepirudin/Refludan).
They are standardized according to Hirudin concentration. The Hirudin protein specific activity can slightly vary from lot to lot (usually range from 14.000 to 16.000 ATU/mg).

PROPERTIES:

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

SYMBOLS:

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