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PLASMA HIRUDIN CONTROL
Ref SC025K

Quality control plasmas at two levels of Hirudin

For in vitro diagnostic use only

Not for Sale in the US

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ENGLISH

INTENDED USE:

Lyophilised plasmas, at a defined Hirudin (Lepirudin) concentration, as measured with the HEMOCLOT Thrombin Inhibitors kit (ref CK002K/L), for the quality control of Hirudin clotting assays, especially when the HEMOCLOT Thrombin Inhibitors kit is used.

SUMMARY AND EXPLANATION:

Hirudin can be used as an anticoagulant for curative indications, mainly in emergency situations. When required, measuring the Hirudin 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 Hirudin concentrations in plasma (especially CK002K/L).

REAGENTS SUPPLIED:

6 vials of 1 mL of human plasma supplemented at 2 different concentrations of Hirudin (3 vials for each concentration).

C1 : ***Control 1***
Human plasma, freeze-dried, supplemented with a low Hirudin concentration (to be restored with **1 mL** distilled water). 3 vials

C2 : ***Control 2:***
Human plasma, freeze-dried, supplemented with a high Hirudin concentration (to be restored with **1 mL** distilled water). 3 vials

The Hirudin concentrations and the acceptance ranges can vary from lot to lot, and are indicated for each lot on the flyer provided within the kit.

Note:
- Control plasmas contain an antibiotic as preservative, and excipients (glycine, stabilizers).
- 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 15 min, while shaking the vial from time to time.
- Homogenise the content before each use.

Stability after reconstitution:

- 48 hours at 2-8°C.
- 24 hours at room temperature (18-25°C).

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:

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

CONCENTRATION:

Each Plasma Hirudin Control kit contains 2 sets of 3 vials with 2 different concentrations of Hirudin (low and high). The exact concentrations may present variations from lot to lot, but they are exactly determined for each lot.
The Hirudin concentrations and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

The control **C1** has usually a concentration of about 1.00 ± 0.15 µg/mL.

The control **C2** has usually a concentration of about 2.00 ± 0.25 µg/mL.

QUALITY CONTROL:

Plasma Hirudin Controls (level 1 and 2) are proposed for the quality control of calibration curves established for the measurements of Hirudin 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 Plasma Hirudin Control kit can be used in association with Plasma Hirudin Standard Low (SC020K) or High (SC020L) for testing Hirudin in plasma, with the **HEMOCLOT Thrombin Inhibitors (Hirudin) kit (#CK002K/L).**

PERFORMANCE CHARACTERISTICS:

Plasma Hirudin Controls allow validating the calibration curve for the measurements of Hirudin in plasma, when the **Hemoclot Thrombin Inhibitors (Hirudin) (ref. CK002K/L)** assay is used.

The Hirudin concentrations, indicated on the flyer, for Control 1 and Control 2, have been measured with the HEMOCLOT Thrombin Inhibitors (Hirudin) (ref CK002K/L) kit.

Plasma Hirudin Controls are standardized by reference to hirudin concentration. The hirudin protein activity can present variations from lot to lot, according to its specific activity (usually in the range 14,000 to 16,000 ATU*/mg)

The target values and the acceptance ranges, indicated on the flyer, are valid for HEMOCLOT Thrombin Inhibitors (Hirudin) assays. The results obtained can vary, when these controls are used with other kits according to the assay reactivity and its standardisation. 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 in the exact laboratory working conditions and for each specific application.

CAUTIONS:

- Like all lyophilised plasmas, the control plasmas 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.

***ATU: Anti-Thrombin Unit**