


**PLASMA
HIRUDIN STANDARD HIGH
SC020L**

For in vitro diagnostic use only

Not for Sale in the US

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ENGLISH
INTENDED USE:

Lyophilised plasmas, at **0 and 5 µg/mL** Hirudin (lepirudin) concentration, for establishing the calibration curve for the clotting assay of Hirudin in human plasmas (Hemoclot Thrombin Inhibitors, #CK002K/L).

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 standards are used for the calibration of clotting assays of Hirudin (CK002K/L).

REAGENTS SUPPLIED:

Each kit contains:

- **Standard 0: Std 0:** 3 vials of 1 ml of normal plasma, lyophilised, without Hirudin (**0 µg/mL**).
- **Standard 5: Std 5:** 3 vials of 1 ml of normal plasma, lyophilised, containing "C" (about **5 µg/mL**) of Hirudin.

The exact concentration of Hirudin can vary from lot to lot, but is exactly indicated for each lot on the flyer provided in the kit.

Note:

- Plasma standards contain an antibiotic as preservative, and excipients (Glycine, stabilizers).
- Each donor unit used for the preparation of plasma standards 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 HIV 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 of Standard 0 or Standard 5:

- Reconstitute each vial with exactly **1 mL** of distilled water.
- Shake strongly until complete dissolution of the content, let stand at room temperature (18-25°C) for 15 min, while shaking the vial from time to time.
- Homogenize the content before each use.

Stability after reconstitution, in the original vial:

When stored in original vials, the reagent is stable:

- 24 hours at room temperature (18-25°C)
- 48 hours at 2-8°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 the calibrator plasma and on a regular basis, in order to keep reagent homogeneity.

PROTOCOL FOR THE CALIBRATION CURVE:

The Hemoclot Thrombin Inhibitors assay uses a twenty fold (**1:20**) plasma dilution for the high range determination. Using the lyophilised plasmas of Hirudin of concentration of **0 µg/mL** and "C", prepare the following calibration curve (manual method), using physiological saline (0.15M Sodium Chloride) or Owren Koller type buffer as diluent. The calibration standards, already diluted twenty fold (**1:20**) are obtained as follows:

Plasma Hirudin concentration (µg/mL)	0	C:4 (about 1.25)	C:2 (about 2.50)	3C:4 (about 3.75)	C (about 5.00)
Plasma 0 µg/mL (µL)	100	75	50	25	0
Plasma Std5 at "C" µg/mL (µL)	0	25	50	75	100
Physiological Saline or Owren Koller Buffer (µL)	1900	1900	1900	1900	1900

Diluted calibrators are stable for at least 2 hours at room temperature.

CALIBRATION RANGE:

The calibration curve covers the range up to about 5.0 µg/ml.

The concentrations have been determined with the **HEMOCLOT Thrombin Inhibitors kit**. The exact concentrations may present variations from lot to lot, but are exactly indicated for each lot on the flyer provided within the kit.

PERFORMANCE CHARACTERISTICS:

Plasma Hirudin Standard High allows establishing the calibration curve for the measurement of Hirudin in plasma, especially with Anti-IIa method when using the **HEMOCLOT Thrombin Inhibitors (ref. CK002K/L) kit (high range protocol)**, the concentration can be measured up to 5 µg/ml).

The **Hirudin Control Plasma (ref SC025K)** can be used in order to obtain a homogeneous quality control system.

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

When used with other kits, results may differ according to the assay reactivity and its standardization: each laboratory must then determine and validate the suitability for use of this calibration plasma application in its specific.

CAUTIONS:

- As like all lyophilised plasmas, the plasmas standards are more or less cloudy after reconstitution. This is due essentially to the lipids which, after lyophilisation, become less soluble and can form a light deposit.
- If necessary, let each vial 10 minutes at room temperature and shake strongly before use in order to homogenize 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