



Plasma Hirudin Standard High

REF SC020L

Std 0 Std 5 3 x 1 mL



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Calibration human plasmas for Hirudin measurements with anti-IIa method (high range).

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INTENDED USE:

The Plasma Hirudin Standard High kit consists of lyophilized human plasmas at 0 and about 5 µg/mL of Hirudin (lepirudin) concentration, for the calibration of the Hirudin assay in human plasmas. It is titrated and optimized for the clotting assay of Hirudin (High range) and more especially for the 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 standards are used for the calibration of clotting assays of Hirudin (CK002K/CK002L).

REAGENTS:

Std 0 Standard 0: Normal plasma, lyophilised, without Hirudin (0 µg/mL).
3 vials of 1 mL.

Std 2 Standard 5: Normal plasma, lyophilised, containing a concentration "C" (about 5 µg/mL) of Hirudin.
3 vials of 1 mL.

The exact concentration of Hirudin 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:

- Plasma standards 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.

Std 0 Std 5 Standard 0 and 5

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 calibrators is related to the corresponding Internal Standard for Hirudin, initially standardized against a pharmaceutical 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).

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 lyophilized 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 Imidazole (AR021A/AR021K) 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 Imidazole Buffer (µL)	1900	1900	1900	1900	1900

PROPERTIES:

The Plasma Hirudin Standard kit is used to establish a calibration curve to cover the range from about 0 to 5 µg/mL of Hirudin in plasma with anti-IIa method, such as those provided by the HEMOCLOT Thrombin Inhibitors (CK002K/CK002L) (high range protocol).

The standard 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.

A new calibration curve should be defined, preferably for each test series, and at least for each new reagent batch, or after analyzer maintenance, or when the measured quality control values fall outside the acceptable range for the method.

LIMITATIONS:

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

SYMBOLS:

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