

**Plasma Hirudin Standard**

REF SC020K CAL0 CAL2 3 x 1 mL

REF SC020L CAL0 CAL5 3 x 1 mL

Human plasma for the calibration of Hirudin assays by anti-IIa method.

Not for Sale in the US

English, Last revision: 12-2019

INTENDED USE:

The Plasma Hirudin Standard kits consist of lyophilized human plasma, spiked with Hirudin at various concentrations, for the calibration of Hirudin assays. They are titrated and optimized for the assay of Hirudin by the anti-IIa clotting technique.

SUMMARY AND EXPLANATION:**Technical:**

These calibrators are used to establish the calibration curve for anti-IIa clotting assay of Hirudin in plasma (HEMOCLOT™ Thrombin Inhibitors, low range / high range).

Clinical:

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.

REAGENTS:

CAL0 Calibrator 0: Lyophilized normal plasma containing no Hirudin.

CAL2 Calibrator 2: Lyophilized normal plasma containing a titrated quantity of Hirudin of approximately 2 µg/mL.

CAL5 Calibrator 5: Lyophilized normal plasma containing a titrated quantity of Hirudin of approximately 5 µg/mL.

Plasma standards contain stabilizing agents.

The standard concentrations may vary slightly from one batch to another. For the assay, see the exact values indicated on the flyer provided with the kit used.

Plasma Hirudin Standard Low

REF SC020K → CAL0 CAL2 3 vials of 1 mL

Plasma Hirudin Standard High

REF SC020L → CAL0 CAL5 3 vials of 1 mL

WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human origin. Whenever human plasma is required for the preparation of these reagents, approved methods are used to test the plasma for the antibodies to HIV 1, HIV 2 and HCV, and for hepatitis B surface antigen, and results are found to be negative. However, no test method can offer complete assurance that infectious agents are absent. Therefore, users of reagents of these types must exercise extreme care in full compliance with safety precautions in the manipulation of these biological materials as if they were infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- Use only the reagents from the same batch of kits.
- Aging studies show that the reagents can be shipped at room temperature without degradation.
- This device of *in vitro* diagnostic use is intended for professional use in the laboratory.

REAGENT PREPARATION:

Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

CAL0 CAL2 CAL5 Reconstitute the contents of each vial with exactly 1 mL of distilled water.

Shake vigorously until complete dissolution while avoiding formation of foam and load it directly on the analyzer following application guide instruction.

For manual method, allow to stabilize for 30 minutes at room temperature (18-25°C), homogenize before use.

This plasmatic reagent can be more or less turbid after reconstitution. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit. If necessary, let each vial 10 minutes at room temperature and shake before use.

STORAGE AND STABILITY:

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.

CAL0 CAL2 CAL5 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- 48 hours at 2-8°C.
- 24 hours days at room temperature (18-25°C).
- Stability on board of the analyzer: see the specific application.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:**Reagents:**

- Distilled water.

Materials:

- Calibrated pipettes.

TRACEABILITY:

The Hirudin calibration plasmas are titrated relative to a reference Internal Standard, initially qualified 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).

QUALITY CONTROL:

The Plasma Hirudin Standard kit are used to establish a calibration curve to measure Hirudin levels by anti-IIa methods, such as those provided by HEMOCLOT™ Thrombin Inhibitors (CK002K/CK002L).

The calibrator target values are determined from multi-instrument (Sysmex CS-series or equivalent) 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.

A new calibration curve should be established, 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 acceptance range for the method.

LIMITATIONS:

- If the calibrators 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 calibrators in its own analytical system.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.

SYMBOLS:

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

Changes compared to the previous version.