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BIOPHEN™ Heparin Calibrator

REF 222001

CAL1 CAL2 CAL3 CAL4 CAL5 4 x 1 mL

IVD

Human plasmas for the calibration of Heparin assays by anti-Xa method.

HYPHEN BioMed

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INTENDED USE:

The BIOPHEN™ Heparin Calibrator kit consists of lyophilized human plasmas, spiked with Low Molecular Weight Heparin (LMWH) at various concentrations, for the calibration of LMWH assays and Unfractionated Heparin (UFH) assays when the superposition (LMWH/UFH) is validated.
It is titrated and optimized for the assay of LMWH by anti-Xa chromogenic assay.

SUMMARY AND EXPLANATION:

Technical:
These calibrators are used to establish the calibration curve of LMWH in plasma by anti-Xa chromogenic assays (BIOPHEN™ Heparin 3, 6 and BIOPHEN™ Heparin LRT).
Clinical:
Heparins (UFH and LMWH) are currently used as an anticoagulant for curative or preventive indications. Measuring the heparin concentration in patients' plasma can be used for monitoring the therapy and adjusting drug dosage.

REAGENTS:

CAL1 **Calibrator 1:** Human Plasma, lyophilized, containing no LMWH (level 1).
CAL2 **Calibrator 2:** Human Plasma, lyophilized, containing a titrated quantity of LMWH of approximately 0.4 IU/mL (level 2).
CAL3 **Calibrator 3:** Human Plasma, lyophilized, containing a titrated quantity of LMWH of approximately 0.8 IU/mL (level 3).
CAL4 **Calibrator 4:** Human Plasma, lyophilized, containing a titrated quantity of LMWH of approximately 1.2 IU/mL (level 4).
CAL5 **Calibrator 5:** Human Plasma, lyophilized, containing a titrated quantity of LMWH of approximately 1.6 IU/mL (level 5).

Calibrator plasmas contain stabilizing agents.

The calibrator 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.

CAL1 CAL2 CAL3 CAL4 CAL5 **4 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.

CAL1 CAL2 CAL3 CAL4 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 10 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 stabilize 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.

CAL1 CAL2 CAL3 CAL4 CAL5 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- **7 days** at 2-8°C.
- **48 hours** at room temperature (18-25°C).
- **Do not freeze.**
- **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 value assignment of calibrators is related to the corresponding International Standard for LMWH from NIBSC in force.

QUALITY CONTROL:

The BIOPHEN™ Heparin Calibrator kit is used to establish a calibration curve to measure Heparin levels in plasma by anti-Xa chromogenic methods, such as those provided by BIOPHEN™ Heparin 3, 6 (221003/221006) or BIOPHEN™ Heparin LRT (221011/221013/221015) kits.
The calibrator target values are determined from multi-reagent (BIOPHEN™ Heparin 3, 6 and BIOPHEN™ Heparin LRT) and 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.
- This kit can also be used for the measurements of UFH when the BIOPHEN Heparin or BIOPHEN™ Heparin LRT kits are used and when the superposition (LMWH/UFH) is validated.
  The use of a single calibration with BIOPHEN™ Heparin Calibrator is possible when Heparin assays are performed with the BIOPHEN Heparin or BIOPHEN™ Heparin LRT reagents, and strictly respecting the operating protocol.

REFERENCES:

1. Gray E. *et al.* Heparin and low-molecular-weight heparin. Thromb Haemost. 2008, 99 :807-818.

SYMBOLS:

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