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BIOPHEN HEPARIN CALIBRATOR Ref 222001

Calibration plasmas for the assay of Heparins with anti-Xa method

For in vitro diagnostic use only

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INTENDED USE:

BIOPHEN Heparin Calibrator is a set of calibration plasmas for Heparin (UFH and LMWH) measurements, using anti-Xa colorimetric assays (BIOPHEN HEPARIN 3 and 6).
BIOPHEN Heparin Calibrator allows calibrating the assays of Low Molecular Weight Heparin (LMWH) using chromogenic anti-Xa methods. It can be also used for calibrating the measurements of Unfractionated Heparin (UFH) when the BIOPHEN Heparin kit is used. Biophen heparin is a chromogenic anti-Xa method developed for measuring homogeneously heparin (UFH) and Low Molecular Weight Heparin (LMWH), using the same calibration curve.

SUMMARY AND EXPLANATION:

Heparins (UFH and LMWH) are currently used as an anticoagulant for curative or preventive indications. Measuring the heparin concentration in patients' plasma allows monitoring the therapy and adjusting drug dosage[7]. BIOPHEN Heparin calibrators are used to establish the calibration curve for chromogenic heparin assays.

REAGENTS SUPPLIED:

20 vials (4 sets of 5 vials) of 1 ml human plasma supplemented with different concentrations of Low Molecular Weight Heparin (LWMH) (4 vials for each concentration).

CAL 1: ***Calibrator 1:*** 1mL 4 vials.
Human plasma, freeze-dried, without any addition of Heparin (level 1 at 0 IU/mL) (to be restored with 1 mL distilled water).

CAL 2: ***Calibrator 2:*** 1mL 4 vials.
Human plasma, freeze-dried, supplemented with Low Molecular Weight Heparin (LMWH) (level 2 at about 0.4 IU/mL) (to be restored with 1 mL distilled water).

CAL 3: ***Calibrator 3:*** 1mL 4 vials.
Human plasma, freeze-dried, supplemented with Low Molecular Weight Heparin (LMWH) (level 3 at about 0.8 IU/mL) (to be restored with 1 mL distilled water).

CAL4 : **Calibrator 4:** 1mL 4 vials.
Human plasma, freeze-dried, supplemented with Low Molecular Weight Heparin (LMWH) (level 4 at about 1.20 IU/mL) (to be restored with 1 mL distilled water).

CAL5 : **Calibrator 5:** 1mL 4 vials.
Human plasma, freeze-dried, supplemented with Low Molecular Weight Heparin (LMWH) (level 5 at about 1.60 IU/mL) (to be restored with 1 mL distilled water).

The exact concentration of LMWH in each vial is indicated on the flyer provided in each kit. The calibration curve covers the range from 0 to 1.6 IU/mL.

Note:
- BIOPHEN Heparin Calibrator plasmas contain an antibiotic as preservative (ciprofloxacin).
- Each donor unit used for the preparation of control plasmas (BIOPHEN Heparin Calibrator) 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, in their original packaging box.
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:

1. 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 30 min, while shaking the vial from time to time.
Homogenise the content before each use.

2. Stability:

Lyophilised:
Kept in the original packaging, the reagents are stable until the expiration date indicated on the labels.

Reconstituted:
- 7 days at 2-8°C.
- 48 hours at room temperature.
- Do not freeze.

***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.

CALIBRATION RANGE:

Each BIOPHEN Heparin calibrator kit contains 4 sets of 5 vials supplemented with increasing concentrations of Low Molecular Weight Heparin (LMWH).
The following values, obtained for one lot of BIOPHEN Heparin Calibrator (on water bath, ACL and/or STA), are provided as an example only.

Calibrator	LMWH concentration (IU/ml)	Intra assay		Inter assay	
		N	CV	N	SD
CAL 1	0	10	na	50	0.01
CAL 2	0.38	10	2.3	50	0.02
CAL 3	0.77	10	0.5	50	0.03
CAL 4	1.14	10	1.0	50	0.05
CAL 5	1.50	10	0.5	50	0.06

The exact concentration may present variations from lot to lot, but it is exactly indicated for each lot, on the flyer provided in the kit.
This concentration is exactly defined against the International Standard for LMWH (NIBSC) (code 85/600).

PERFORMANCE CHARACTERISTICS:

BIOPHEN Heparin calibrator plasmas allow establishing the calibration curve for the measurement of Heparin (UFH or LMWH) in plasma, especially with Anti-Xa methods (such as BIOPHEN Heparin 3 (ref. 221003) or BIOPHEN Heparin 6 (Ref. 221006))[6]. The BIOPHEN quality control plasmas (BIOPHEN LMWH Control Plasma, ref 223001, and BIOPHEN LMWH Control Low, ref 223701) can be used in order to obtain an homogeneous quality control system.
The currently available anti-Xa methods, used for the measurement of Heparin concentrations in plasma, offer a sensitivity threshold of about 0.05 IU/mL.

CAUTIONS:

- Like all lyophilised plasmas, the calibration plasmas from the BIOPHEN Heparin Calibrator 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.

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