

CE **BIOPHEN**
UFH CALIBRATOR
Ref A222301



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

For in vitro diagnostic use only

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ENGLISH

INTENDED USE:

BIOPHEN UFH Calibrator is a set of calibration plasmas for Unfractionated Heparin (UFH) measurements, using anti-Xa colorimetric assays (BIOPHEN HEPARIN 3 and 6).

BIOPHEN UFH Calibrator allows calibrating the measurements of Unfractionated Heparin (UFH) when the BIOPHEN Heparin kit is used.

REAGENTS SUPPLIED:

20 vials (4 sets of 5 vials) of 1 ml human plasma supplemented with different concentrations of Unfractionated Heparin (UFH) (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 Unfractionated Heparin (UFH) (level 2 at about 0.35 IU/mL) (to be restored with 1 mL distilled water).

CAL 3: Calibrator 3 1ml 4 vials.

Human plasma, freeze-dried, supplemented with Unfractionated Heparin (UFH) (level 3 at about 0.70 IU/mL) (to be restored with 1 mL distilled water).

CAL 4: Calibrator 4: 1ml 4 vials.

Human plasma, freeze-dried, supplemented with Unfractionated Heparin (UFH) (level 4 at about 1.05 IU/mL) (to be restored with 1 mL distilled water).

CAL 5: Calibrator 5: 1ml 4 vials.

Human plasma, freeze-dried, supplemented with Unfractionated Heparin (UFH) (level 5 at about 1.40 IU/mL) (to be restored with 1 mL distilled water).

The exact concentration of UFH in each vial is indicated on the flyer provided in each kit. The calibration curve covers the range from 0 to 1.40 IU/mL.

Note:

- BIOPHEN UFH Calibrator plasmas contain an antibiotic as preservative (ciprofloxacin)
- Each donor unit used for the preparation of control plasmas (BIOPHEN UFH 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. 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:

- 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.

Stability after reconstitution:

- 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 UFH calibrator kit contains 4 sets of 5 vials supplemented with increasing concentrations of Unfractionated Heparin (UFH). The following values, obtained for one lot of BIOPHEN UFH Calibrator, are provided as an example only.

Calibrator	Concentration in UFH (IU/ml)	N	SD
CAL 1	0	28	0
CAL 2	0.38	28	0.02
CAL 3	0.74	28	0.04
CAL 4	1.08	28	0.06
CAL 5	1.42	28	0.08

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 5th International Standard for UFH (NIBSC) (code 97/578).

PERFORMANCE CHARACTERISTICS:

BIOPHEN UFH calibrator plasmas allow establishing the calibration curve for the measurement of Heparin (UFH) in plasma, especially with Anti-Xa methods (such as BIOPHEN Heparin 3 (ref. A221003) or BIOPHEN Heparin 6 (Ref. A221006)). The calibration curve obtained covers the usual concentrations currently observed during Heparin (UFH) therapy. 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 of the BIOPHEN UFH Calibrator Kit 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 a contamination must be rejected.

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6560 Gove Court
Mason, OH 45040

Phone: 513-770-1991
Web: www.aniara.com

Toll Free: 866-783-3797

FAX: 513-573-9241
Email: info@aniara.com