BIOPHEN™ UFH Calibrator

REF 222301

CAL1 | CAL2 | CAL3 | CAL4 | CAL5 4 x 1 mL

IVD

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

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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.

SUMMARY AND EXPLANATION:

Technical:
BIOPHEN™ UFH calibrator is used to establish the calibration curve for chromogenic heparin[1] assays.
Clinical:
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[2].

REAGENTS:

CAL1 **Calibrator 1:** Lyophilized human plasma without any addition of Heparin, at 0 IU/mL (level 1).
4 vials of 1 mL
CAL2 **Calibrator 2:** Lyophilized human plasma containing a titrated quantity of UFH, of approximately 0.35 IU/mL (level 2).
4 vials of 1 mL
CAL3 **Calibrator 3:** Lyophilized human plasma containing a titrated quantity of UFH, of approximately 0.70 IU/mL (level 3).
4 vials of 1 mL
CAL4 **Calibrator 4:** Lyophilized human plasma containing a titrated quantity of UFH, of approximately 1.05 IU/mL (level 4).
4 vials of 1 mL
CAL5 **Calibrator 5:** Lyophilized human plasma containing a titrated quantity of UFH, of approximately 1.40 IU/mL (level 5).
4 vials of 1 mL

Calibrator plasmas contain an antibiotic as preservative (ciprofloxacin).

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. The calibration curve covers the range from 0 to 1.4 IU/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.
- 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.
- The stability studies at 30°C show that the reagents can be shipped at room temperature without damage.
- 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 UFH from NIBSC in force.

QUALITY CONTROL:

BIOPHEN™ UFH Calibrator kit is used for the calibration of Heparin (UFH) assays in plasma by anti-Xa chromogenic methods, such as BIOPHEN™ Heparin 3, 6 (221003/221006)[1].
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, 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.

The following example shows the Unfractionated Heparin (UFH) concentrations indicated for one lot of BIOPHEN™ UFH Calibrator (obtained on water bath, ACL and/or STA):

Calibrator	UFH concentration (IU/ml)	Intra assay		Inter assay	
		N	CV	N	SD
CAL 1	0	10	na	28	0
CAL 2	0.38	10	1.4	28	0.02
CAL 3	0.74	10	1.0	28	0.04
CAL 4	1.08	10	0.5	28	0.06
CAL 5	1.42	10	0.5	28	0.08

The currently available anti-Xa methods, used for the measurement of heparins and their analogues in plasma, offer a sensitivity threshold of about 0.05 IU/mL.

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.

REFERENCES:

1. Toulon & al, Monitoring heparin therapy using activated partial thromboplastin time – results of a multicenter trial establishing the therapeutic range for silimat, a reagent with high sensitivity to heparin", Thromb haemost, 80:104-108 (1998).
2. Wood, Weitz, Low molecular weight heparins, New England Journal of Medicine, 337:10, 688-698 (1997).
3. Richardson J.H. and Backley W.E. Eds. Bios. Microbiological and Biomedical laboratories. US. Dept. and Human Services, Public Health Service, HHS publication (CDC) 84-8395, Washington, D.C. (1984).
4. National Committee for Clinical Laboratory Standards Specifications for reagent water used in the clinical lab NCCLS Approved Standard: ASC-3.
5. Westgard J.O., Barry P.L. Cost effective Quality Managing for managing the quality and the Productivity of Analytical AACC Press (1986).
6. Leirozovicz A., Hought M.C, Chapuis FX, Samama, Boissel JP Low molecular weight heparin in prevention of perioperative thrombosis. Br Med. J 305, 913 (1992).
7. Hemker H.C., Beguin S., The mode of action of heparin in vitro and in vivo. In: heparin platelet polysaccharides. Plenum Press. New York 221-230 (1992).
8. 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.