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

HYPHEN BioMed

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INTENDED USE:

The BIOPHEN™ UFH Calibrator kit consists of lyophilized human plasmas, overloaded with Unfractionated Heparin (UFH) at various concentrations, for the calibration of Unfractionated Heparin (UFH) assays.
It is titrated and optimized for the assay of Unfractionated Heparin (UFH) by anti-Xa chromogenic assay and, more specifically, for the BIOPHEN Heparin 3 and 6 (221003/221006) or BIOPHEN™ Heparin LRT (221011/221013/221015).

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 can be used for monitoring the therapy and adjusting drug dosage. These calibrators are used to establish the calibration curve of UFH chromogenic assays.

REAGENTS:

CAL1 **Calibrator 1:** Lyophilized human plasma containing a titrated quantity of UFH of 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.

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

WARNINGS AND PRECAUTIONS:

- Calibrator plasmas contain stabilizing agents.
- Each pouch of human plasma used for kit preparation was obtained from healthy donors. Each plasma used was screened for the presence of the HBs antigen, of anti-HIV1, anti-HIV2 and anti-HCV antibodies, using approved methods, and found to be negative. Nevertheless, no tests can totally exclude the presence of infectious agents. For this reason, every precaution required for the use of potentially infectious products should be take when handling and disposing of plasma.
- Waste should be disposed of in accordance with applicable local regulations.
- Handle the reagents with care to avoid contamination during use. If possible, avoid reagent evaporation during use by limiting the liquid-air exchange surface. Evaporation reduces the reagent's stability in the analyzer.
- To ensure reagent stability, seal the vials after use with their respective caps, or close the plastic micro-containers into which the plasmas may have been transferred, depending on the protocol used.
- Aging studies, conducted over a 3-week period at 30°C, show that the reagents can be shipped at room temperature over a short period of time, without degradation.
- For *in vitro* diagnostic use.

REAGENT PREPARATION AND STABILITY:

The reagents are lyophilized under vacuum in their vials. To avoid any product loss when opening the vial of lyophilized reagents, gently remove the freeze-drying stopper.

CAL1 | CAL2 | CAL3 | CAL4 | CAL5
Reconstitute the contents of each vial with exactly **1 mL distilled water**, shake vigorously until fully dissolved.
Allow to stabilize for 30 min. at room temperature (18-25°C), shaking occasionally.
Homogenize prior to use.
Reagent stability after reconstitution, free from any contamination or evaporation, and stored in the original vial, is of:

- **7 days** at 2-8°C.
- **48 hours** at room temperature (18-25°C).
- **Do not freeze.**

STORAGE CONDITIONS:

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.

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.

PROPERTIES:

The BIOPHEN™ UFH Calibrator is used to establish a calibration curve to measure the Heparin (UFH) in plasma by Anti-Xa methods, such as those provided by BIOPHEN Heparin 3 (221003), BIOPHEN Heparin 6 (221006) and BIOPHEN™ Heparin LRT (221011/221013/221015).
The calibrator target values are determined from multi-reagent (BIOPHEN Heparin 3 (221003), BIOPHEN Heparin 6 (221006) and BIOPHEN™ Heparin LRT (221011/221013/221015)) and multi-instrument (Sysmex CS-series or equivalent) tests.
The calibration curve obtained covers the usual concentrations currently observed during Heparin (UFH) therapy.
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 defined, 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 acceptable range for the method.

LIMITATIONS:

- Like all lyophilized plasmas, calibration plasmas are more or less turbid once resuspended. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit.
- Any plasma displaying a coagulum or showing signs of bacterial or fungal contamination must be rejected.
- 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.

REFERENCES:

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2. National Committee for Clinical Laboratory Standards Specifications for reagent water used in the clinical lab NCCLS Approved Standard: ASC-3.
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4. Leirozovicz A., Hought M.C, Chapuis FX, Samama, Boissel JP Low molecular weight heparin in prevention of perioperative thrombosis. Br Med. 1992.
5. Hemker H.C., Beguin S., The mode of action of heparin in vitro and in vivo. In: heparin platelet polysaccharides. Plenum Press. New York. 1992.

SYMBOLS:

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