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BIOPHEN UFH CONTROL PLASMA Ref 223101

Human plasmas at two levels of Unfractionated Heparin (UFH) for the quality control of Heparin measurements with anti-Xa methods

For in vitro diagnostic use only

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INTENDED USE:

Biophen UFH Control kit is a set of control plasmas for the quality control of Unfractionated Heparin (UFH) measurements, using anti-Xa colorimetric assays (BIOPHEN HEPARIN 3 and 6).

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]. These control plasmas are used for the quality control of UFH chromogenic assays[6].

REAGENTS SUPPLIED:

12 vials of 1 mL of human plasma supplemented at 2 different concentrations of Unfractionated Heparin (UFH) (6 vials for each concentration).

C1 : ***Control 1***
Human plasma, freeze-dried, supplemented with Unfractionated Heparin (UFH) (level 1 at about 0.20 IU/mL) (to be restored with 1 mL distilled water).
6 vials of 1 mL

C2 : ***Control 2:***
Human plasma, freeze-dried, supplemented with Unfractionated Heparin (UFH) (level 2 at about 0.50 IU/mL) (to be restored with 1 mL distilled water).
6 vials of 1 mL

The Unfractionated Heparin (UFH) concentrations and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

Note:

- BIOPHEN UFH Control plasmas contain an antibiotic as preservative (ciprofloxacin)
- Each donor unit used for the preparation of control plasmas (BIOPHEN UFH Control) is a human plasma, which has been tested with registered methods for the presence of Hepatitis B Surface Antigen, Hepatitis C Antibodies (HCV) 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:

C1:

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 of control plasma C1, kept in its original vial:

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

C2:

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 of control plasma C2, kept in its original vial:

- 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.

TRACEABILITY ON CONTROL MATERIALS:

BIOPHEN UFH Controls are calibrated against an International Standard from NIBSC.

CONCENTRATION:

Each BIOPHEN UFH Control kit contains 2 sets of 6 vials with 2 different concentrations of Unfractionated Heparin (UFH). The exact concentration may present variations from lot to lot, but it is exactly determined for each lot.
The Unfractionated Heparin (UFH) concentrations and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

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

BIOPHEN UFH Control	UFH (IU/ml)	Acceptance range (IU/ml)	Intra assay		Inter assay	
			N	CV	N	SD
Level 1	0.21	0.11-0.31	10	1.1	30	0.01
Level 2	0.51	0.36-0.66	10	0.7	30	0.02

The control **C1** has usually a concentration between 0.20 ± 0.10 UI/mL.

The control **C2** has usually a concentration between 0.50 ± 0.10 UI/mL.

QUALITY CONTROL:

BIOPHEN UFH Control Plasmas (level 1 and 2) are proposed for the quality control of calibration curves established for measurements of Unfractionated Heparin (UFH) in plasma. They allow validating these calibration curves. They are especially useful for controlling the stability of the calibration curves, from run to run, when using a same lot of reagents.
If controls are out of the acceptance range, the test series can be invalid, and the assay should be rerun. Check all the components of the test system, before rerunning the assay.

The BIOPHEN UFH control kit, which contains plasma at 2 different Unfractionated Heparin (UFH) concentrations, can be used in association with BIOPHEN Heparin Calibrator (#222001) for testing Unfractionated Heparin (UFH) in plasma

SPECIFIC PERFORMANCE CHARACTERISTICS:

BIOPHEN UFH Control plasmas allow validating the calibration curve for the measurement of Unfractionated Heparin (UFH) in plasma, especially with Anti-Xa methods (such as BIOPHEN Heparin 3 (ref. 221003) or BIOPHEN Heparin 6 (Ref. 221006)).

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

CAUTIONS:

- Like all lyophilised plasmas, the control plasmas from the BIOPHEN UFH Control 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 for 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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