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BIOPHEN LMWH CONTROL PLASMA Ref 223001

Human plasmas at two levels of Low Molecular Weight Heparin (LMWH) for the quality control of Heparin measurements with anti-Xa methods

For in vitro diagnostic use only

Last revision: 24/06/2014

ENGLISH

INTENDED USE:

Biophen LMWH Control Kit is a set of control plasmas for the quality control of Low Molecular Weight Heparin (LMWH) measurements, using anti-Xa colorimetric assays (BIOPHEN HEPARIN 3 and 6).
These control plasmas are within the usual therapeutic range recommended for Low Molecular Weight Heparin (LMWH).

REAGENTS SUPPLIED:

12 vials of 1 mL of human plasma supplemented at 2 different concentrations of Low Molecular Weight Heparin (LMWH) (6 vials for each concentration).

C3 : ***Control 3:*** 6 vials of 1 mL
Human plasma, freeze-dried, supplemented with Low Molecular Weight Heparin (LMWH) (level 3 at about 0.80 IU/mL) (to be restored with 1 mL distilled water.

C4 : ***Control 4:*** 6 vials of 1 mL
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).

The Low Molecular Weight Heparin (LMWH) concentrations and the acceptance ranges are indicated for each lot on the flyer provided within the kit.

Note:

- BIOPHEN LMWH Control plasmas contain an antibiotic as preservative (ciprofloxacin)
- Each donor unit used for the preparation of control plasmas (BIOPHEN LMWH 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. 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 of C3 and C4:

- 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 for control plasma C3 and C4:

Kept in their original vial, the reagents are stable for:

- 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 LMWH Controls are calibrated against an International Standard for LMWH from NIBSC.

CONCENTRATION:

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

The following example shows the Low Molecular Weight Heparin (LMWH) concentrations indicated for one lot of BIOPHEN LMWH Control:

BIOPHEN LMWH Control	LMWH Concentration (IU/ml)	Acceptance range (IU/ml)	N	SD
Level 3	0.79	0.69-0.89	69	0.03
Level 4	1.25	1.10-1.40	69	0.05

The control **C3** has usually a concentration of 0.80 ± 0.10 IU/mL.

The control **C4** has usually a concentration of 1.20 ± 0.15 IU/mL.

QUALITY CONTROL:

BIOPHEN LWMH Control Plasmas (level 3 and 4) are proposed for the quality control of calibration curves established for the measurements of Low Molecular Weight Heparin (LMWH) 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 LMWH control kit, which contains plasmas at 2 different Low Molecular Weight Heparin (LMWH) concentrations, can be used in association with BIOPHEN Heparin Calibrator (#222001) for testing Low Molecular Heparin in plasma.

PERFORMANCE CHARACTERISTICS:

BIOPHEN LMWH Control plasmas allow validating the calibration curve for the measurements of Low Molecular Weight Heparin (LMWH) in plasma, especially with Anti-Xa methods (such as BIOPHEN Heparin 3 (ref. 221003) or BIOPHEN Heparin 6 (Ref. 221006)). The calibration curve obtained covers the usual concentrations currently observed during Low Molecular Weight Heparin (LMWH) therapy.

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 LMWH 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 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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