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BIOPHEN LMWH CONTROL LOW CII Ref 224401

Human plasma supplemented with Low Molecular Weight Heparin (LMWH) for the quality control of Heparin measurements with anti-Xa methods

For in vitro diagnostic use only

Last revision: 22/04/2011

ENGLISH

INTENDED USE:

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

REAGENT SUPPLIED:

12 vials of 1 mL of human plasma supplemented, at a defined concentration, with Low Molecular Weight Heparin (LMWH).

CII : ***Control II:*** 12 vials of 1 mL
Human plasma, freeze-dried, supplemented with Low Molecular Weight Heparin (LMWH) (level II at about 0.50 IU/mL) (to be restored with 1 mL distilled water).

The Low Molecular Weight Heparin (LMWH) concentration and the acceptance range are indicated on the flyer provided within the kit.

Note:
- It contains an antibiotic as preservative.
- Each donor unit used for the preparation of the control plasma 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 REAGENT:

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:

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 Control Low CII is calibrated against an International Standard for LMWH from NIBSC.

CONCENTRATION:

Each BIOPHEN LMWH Control Low CII kit contains 1 set of 12 vials supplemented with a defined concentration 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) concentration and the acceptance range are indicated for each lot on the flyer provided within the kit.

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

BIOPHEN LMWH Control Low	**LMWH Concentration (IU/ml)**	**Acceptance range (IU/ml)**	**N**	**SD**
Level II	0.50	0.40-0.60	43	0.03

The control **CII** has usually a concentration of 0.50 ± 0.15 IU/mL.

QUALITY CONTROL:

BIOPHEN LWMH Control Low CII kit (level II) is proposed for the quality control of calibration curves established for the measurements of Low Molecular Weight Heparin (LMWH) in plasma. It allows validating these calibration curves. It is especially useful for controlling the stability of the calibration curves, from run to run, when using a same lot of reagents.

If control is 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 low CII kit, which contains a set of plasmas at a determined Low Molecular Weight Heparin (LMWH) concentration, can be used in association with BIOPHEN Heparin Calibrator (#222001) for testing Low Molecular Weight Heparin in plasma.

PERFORMANCE CHARACTERISTICS:

BIOPHEN LMWH Control Low CII plasma allows 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, this control plasma is 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, leave 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.

REFERENCES :

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