

BIOPHEN ORGARAN® CALIBRATOR Ref A22201-RUO

Calibration plasmas for the assay of Sodium Danaparoid (Orgaran®)
with anti-Xa methods

**FOR RESEARCH USE ONLY.
NOT FOR USE IN DIAGNOSTIC PROCEDURES.**



Manufactured By: HYPHEN BioMed

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INTENDED USE:

BIOPHEN Orgaran® Calibrator is a set of calibration plasmas proposed for Sodium Danaparoid (ORGARAN®) measurements, using anti-Xa colorimetric assays (BIOPHEN HEPARIN 3 and 6). **This kit is for research use only and should not be used for patient diagnosis or treatment.**

REAGENTS SUPPLIED:

20 vials (4 sets of 5 vials) of 1 ml human plasma supplemented with different concentrations of Sodium Danaparoid (Orgaran®) (4 vials for each concentration).

CAL 1: Calibrator 1: 1mL 4 vials

Human plasma, freeze-dried, without any addition of Sodium Danaparoid (Orgaran®) (level 1 at 0 IU/mL) (to be restored with 1 mL distilled water).

CAL 2: Calibrator 2 1mL 4 vials

Human plasma, freeze-dried, supplemented with Sodium Danaparoid (Orgaran®) (level 2 at about 0.4 IU/mL) (to be restored with 1 mL distilled water).

CAL 3: Calibrator 3 1mL 4 vials

Human plasma, freeze-dried, supplemented with Sodium Danaparoid (Orgaran®) (level 3 at about 0.8 IU/mL) (to be restored with 1 mL distilled water).

CAL 4: Calibrator 4 1mL 4 vials

Human plasma, freeze-dried, supplemented with Sodium Danaparoid (Orgaran®) (level 4 at about 1.2 IU/mL) (to be restored with 1 mL distilled water).

CAL 5: Calibrator 5 1mL 4 vials

Human plasma, freeze-dried, supplemented with Sodium Danaparoid (Orgaran®) (level 5 at about 1.6 IU/mL) (to be restored with 1 mL distilled water).

The exact concentration of Sodium Danaparoid (Orgaran®) in each vial is indicated on the flyer provided in each kit.

The calibration curve covers the range from 0 to 1.6 IU/mL.

Note:

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

- 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:

- 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.

CALIBRATION RANGE:

Each BIOPHEN Orgaran® Calibrator kit contains 4 sets of 5 vials supplemented with increasing concentrations of Sodium Danaparoid (Orgaran®). The exact concentration may present variations from lot to lot, but it is exactly indicated for each lot, on the flyer provided in the kit. This concentration is exactly defined against a Sodium Danaparoid (Orgaran®) reference material (from drug manufacturer).

PERFORMANCE CHARACTERISTICS:

BIOPHEN Orgaran® Calibrator plasmas allow establishing the calibration curve for the measurement of Sodium Danaparoid (Orgaran®) in plasma, especially with Anti-Xa methods (such as BIOPHEN Heparin 3 (ref. A221003) or BIOPHEN Heparin 6 (Ref. A221006)).

The currently available anti-Xa methods, used for the measurement of Sodium Danaparoid (Orgaran®) concentrations in plasma, offer a sensitivity threshold of about 0.05 IU/mL.

CAUTIONS:

- Like all lyophilised plasmas, the calibration plasmas from the BIOPHEN Orgaran® Calibrator 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.
- **The results obtained should be for research purposes only and not used for patient diagnosis or treatment.**

REFERENCES :

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