

BIOPHEN ORGARAN® CONTROL Ref A223501-RUO

Control plasmas for the quality control of Sodium Danaparoid (Orgaran®) measurements with anti-Xa methods

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

ANIARA

Manufactured By: HYPHEN BioMed

Last revision: 21/04/2011

INTENDED USE:

BIOPHEN Orgaran® Control is a set of control plasmas proposed for the quality control of 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:

12 vials of 1 ml human plasma supplemented with 2 different concentrations of Sodium Danaparoid (Orgaran®) (6 vials for each concentration).

- **C1:** 1mL 6 vials
Human plasma, freeze-dried, supplemented with Sodium Danaparoid (Orgaran®) (level 1 at about 0.5 IU/mL) (to be restored with 1 mL distilled water)
- **C2:** 1mL 6 vials
Human plasma, freeze-dried, supplemented with Sodium Danaparoid (Orgaran®) (level 2 at about 1.0 IU/mL) (to be restored with 1 mL distilled water)

Note:

1. BIOPHEN Orgaran® Control plasmas contain an antibiotic as preservative (ciprofloxacin)
2. Each donor unit used for the preparation of control plasmas (BIOPHEN Orgaran® Control) 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 of C1 and 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 after reconstitution for control plasma C1 and C2:

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.

CONCENTRATION:

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

BIOPHEN Orgaran® Controls are calibrated against a Sodium Danaparoid (Orgaran®) reference material, from drug manufacturer.

The following example shows the Sodium Danaparoid (Orgaran®) concentrations indicated for one lot of BIOPHEN Orgaran® Control:

BIOPHEN Orgaran® Control	Sodium Danaparoid (Orgaran®) concentration (IU/mL)
Level 1	0.50
Level 2	1.00

QUALITY CONTROL:

BIOPHEN Orgaran® Control Plasmas (level 1 and 2) are proposed for the quality control of calibration curves established for measurements of Sodium Danaparoid (Orgaran®) 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 Orgaran® control kit, which contains plasmas at 2 different Sodium Danaparoid (Orgaran®) concentrations, can be used in association with BIOPHEN Orgaran® Calibrator (#A222201) for testing specifically Sodium Danaparoid (Orgaran®) in plasma.

SPECIFIC PERFORMANCE CHARACTERISTICS:

BIOPHEN Orgaran® Control plasmas allow validating 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 concentrations of heparins and their analogues (such as Sodium Danaparoid (Orgaran®)) in plasma, offer a sensitivity threshold of about 0.05 IU/mL.

CAUTIONS:

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

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D.750.02/BI/3501/RUO

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