BIOPHEN™ Orgaran® Control

CE

IVD

REF 223501

C1 C2 6 x 1 mL

Human plasmas for the quality control
of Danaparoid Sodium (Orgaran®) measurements by anti-Xa method.

Not for Sale in the US

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INTENDED USE:

The BIOPHEN™ Orgaran® Control kit consists of lyophilized human plasmas, spiked with Danaparoid Sodium (Orgaran®) at various concentrations, for the quality control of Danaparoid Sodium (Orgaran®) assays.
It is titrated and optimized for the assay of Danaparoid Sodium (Orgaran®) by anti-Xa chromogenic technique.

SUMMARY AND EXPLANATION:

Technical:
These control plasmas are used for the quality control of Danaparoid Sodium anti-Xa chromogenic assays in plasma (BIOPHEN™ Heparin 3, 6 and BIOPHEN™ Heparin LRT).
Clinical:
Danaparoid Sodium (Orgaran®) is a polysaccharide anticoagulant, used as an alternative therapy to Unfractionated Heparin (UFH) or Low Molecular Weight Heparin (LMWH) when these latter drugs are contra-indicated. Measuring the Danaparoid Sodium (Orgaran®) concentration in patients' plasma may be used for monitoring the therapy and adjusting drug dosage.

REAGENTS:

C1 **Control 1:** Lyophilized human plasma, containing a titrated quantity of Danaparoid Sodium (Orgaran®) of approximately 0.5 U/mL.
C2 **Control 2:** Lyophilized human plasma, containing a titrated quantity of Danaparoid Sodium (Orgaran®) of approximately 1.0 U/mL.

Control plasmas contain stabilizing agents.

The control concentrations may vary slightly from one batch to another. For the assay, see the exact values provided on the flyer provided with the kit used.

C1 C2 **6 vials of 1 mL.**

WARNINGS AND PRECAUTIONS:

- Some reagents provided in these kits contain materials of human origin. Whenever human plasma is required for the preparation of these reagents, approved methods are used to test the plasma for the antibodies to HIV 1, HIV 2 and HCV, and for hepatitis B surface antigen, and results are found to be negative. However, no test method can offer complete assurance that infectious agents are absent. Therefore, users of reagents of these types must exercise extreme care in full compliance with safety precautions in the manipulation of these biological materials as if they were infectious.
- Waste should be disposed of in accordance with applicable local regulations.
- Use only the reagents from the same batch of kits.
- Aging studies show that the reagents can be shipped at room temperature without degradation.
- This device of *in vitro* diagnostic use is intended for professional use in the laboratory.

REAGENT PREPARATION:

Gently remove the freeze-drying stopper, to avoid any product loss when opening the vial.

C1 C2 Reconstitute the contents of each vial with exactly **1 mL of distilled water.**
Shake vigorously until complete dissolution while avoiding formation of foam and load it directly on the analyzer following application guide instruction.
For manual method, allow to stabilize for 10 minutes at room temperature (18-25°C), homogenize before use.

This plasmatic reagent can be more or less turbid after reconstitution. This turbidity is mainly due to plasma lipids that, after freeze-drying, become "less" soluble and may form a slight deposit. If necessary, let each vial stabilize 10 minutes at room temperature and shake before use.

STORAGE AND STABILITY:

Unopened reagents should be stored at 2-8°C in their original packaging. Under these conditions, they can be used until the expiry date printed on the kit.

C1 C2 Reagent stability after reconstitution, free from any contamination or evaporation, and stored closed, is of:

- **7 days** at 2-8°C.
- **48 hours** at room temperature (18-25°C).
- **Do not freeze.**
- **Stability on board of the analyzer: see the specific application.**

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

Reagents:
- Distilled water.

Materials:
- Calibrated pipettes.

TRACEABILITY:

BIOPHEN™ Orgaran® Control are qualified relative to an Internal Standard for Orgaran®, initially qualified against a fresh preparation of Orgaran®, diluted in normal human citrated plasma.

QUALITY CONTROL:

The BIOPHEN™ Orgaran® Control kit is used for the quality control of Danaparoid Sodium (Orgaran®) assays in plasma by anti-Xa chromogenic methods, such as those provided by the BIOPHEN™ Heparin 3, 6 (221003/221006) or BIOPHEN™ Heparin LRT (221011/221013/221015) kits.
The control target values are determined from multi-reagent (BIOPHEN™ Heparin 3, 6 and BIOPHEN™ Heparin LRT) and multi-instrument (Sysmex CS-series or equivalent) tests.
The use of quality controls serves to validate method compliance, along with between-series assay homogeneity for a given batch of reagents.
Include the quality controls with each series, as per good laboratory practice, in order to validate the test.
If the controls fall outside of the acceptance range, the series of assays must be invalidated and the analyses repeated. Check all system parameters before repeating the series.

LIMITATIONS:

- If the controls are used under measurement conditions other than those validated by HYPHEN BioMed, the test results may vary. The laboratory is responsible for validating the use of these controls in its own analytical system.
- Any reagent presenting an unusual appearance or showing signs of contamination must be rejected.

REFERENCES:

1. David A. Garcia *et al.* Antithrombotic Therapy and Prevention of Thrombosis, 9th ed : American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. CHEST. 2012.
2. Theodore E. Warkentin and Julia A. M. Anderson. How I treat patients with a history of heparin-induced thrombocytopenia. Blood. 2016.

SYMBOLS:

Symbols used and signs listed in the ISO 15223-1 standard, see Symbol definitions document.