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IVD

BIOPHEN™ Orgaran® Control

REF 223501

C1 C2 6 vials x 1 mL

English, revision: 11-2023

INTENDED USE:

For quality control of Orgaran® (Danaparoid Sodium) assays, using a quantitative automated method.
This device of *in vitro* diagnostic use is intended for professional use in the laboratory.

SUMMARY AND EXPLANATION:

Technical:
These controls are proposed for the quality control of Danaparoid Sodium anti-Xa chromogenic assays in plasma (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 Lyophilized human plasma containing approximately 0.5 U/mL of Danaparoid Sodium (Orgaran®).
C2 Lyophilized human plasma containing approximately 1.0 U/mL of Danaparoid Sodium (Orgaran®).

Control plasmas contain stabilizing agents.

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

The product is classified as non-hazardous and is not subject to labeling according to EC Regulation No. 1272/2008 [CLP].

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.
- Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
- Summary of Safety and Performance (SSP) is available in the European database on medical devices (see Eudamed public website: https://ec.europa.eu/tools/eudamed or on request to HYPHEN BioMed).

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.

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.
- **60 days** frozen at -20°C or less*
- **Stability on board of the analyzer: see the specific Application Guide.**

*Thaw only once, as rapidly as possible at 37°C and use immediately.

REAGENTS AND MATERIALS REQUIRED BUT NOT PROVIDED:

- Laboratory material.

TRACEABILITY:

Lot to lot variability measured on 3 lots is: %CV ≤ 10%.
Controls are traceable to European Pharmacopoeia (Ph. Eur.) Reference Standard for Danaparoid Sodium.
Certificate of traceability and uncertainty is available on the HYPHEN BioMed website:

Uncertainty			
C1	± 0.03 U/mL	C2	± 0.03 U/mL

QUALITY CONTROL:

For quality control of Danaparoid Sodium (Orgaran®) assays by anti-Xa chromogenic method, with the BIOPHEN™ Heparin LRT (221011/221013/221015) kits.
The target values are determined from multi-reagent and multi-instrument 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 no limpid 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.

e-IFU (other languages) are available on www.hyphen-biomed.com.
For customer support or Application Guides, please contact your local provider or distributor (see www.hyphen-biomed.com).

Changes compared to the previous version.

The following symbols may appear on the product labeling:

REF	Catalogue number	LOT	Batch code	IVD	*In-vitro* diagnostic medical device
Rx	Numerical < x> identification of reagent		See instructions for use	WHO STD	WHO standard code
	Temperature limitation		Manufacturer	YYYY-MM-DD	Use by
CE XXXX	CE marking of conformity with notified body ID number.	→	Reconstitution volume	CONTENTS	Contents
Cx	Numerical < x> identification of control	i-MA	See instructions in Method Application guide	CONTAINS	Contains
EXP	Expiration date	Σ	Contains sufficient for <n> tests	UNIT	Measurement unit
TARGET VALUE	Target Value		Keep away from sunlight and heat	CALx	Numerical < x> identification of calibrator
UDI	Unique Device Identifier	BIO	Contains biological material of animal origin		Contains human blood or plasma derivatives
DANGER	Danger	WARNING	Warning	UKCA	UKCA marking of conformity
	Biological risks	ACCEPTANCE RANGE	Acceptance range		