

TECHNOVIEW Orgaran^{®*}






For research use only



GB

REF	5090110	TECHNOVIEW Orgaran ^{®*} CAL Set	5 x 1 mL
REF	5090112	TECHNOVIEW Orgaran ^{®*} CONT L	5 x 1 mL
REF	5090114	TECHNOVIEW Orgaran ^{®*} CONT H	5 x 1 mL

Symbols key

	Manufacturer		Expiry date
	Storage temperature		Consult instructions for use
AQUA	Distilled water		Determinations
BUF	Reaction buffer	LOT	Lot
CAL	Calibrator	MTP	Microtiter plate
CONJ	Conjugate	REF	Catalogue number
CONT	Control	RTU	Ready to use
DIL	Dilute or dissolve in	STOP	Stop solution
INC	Incubation buffer	SUB	Substrate
RUO	For research use only	WASH	Washing solution concentrate



PRODUCT DESCRIPTION

INTENDED USE

TECHNOVIEW Organan® Calibrator Set is a set of calibration plasmas and TECHNOVIEW Organan® Control Plasma is a set of low and high control plasmas for calibration and the quality control of Sodium Danaparoid (Organan®) measurements titrated and optimised using anti-Xa assays.

Sodium Danaparoid (Organan®) is a polysaccharide anticoagulant, used as an alternative therapy to Heparin or low molecular weight Heparin (LMWH), when these latter drugs are contraindicated.

COMPOSITION

TECHNOVIEW Organan® Calibrator and Control Plasma are prepared from citrated plasmas supplemented with different concentrations of Sodium Danaparoid (Organan®). The plasma contains stabilizers but no bactericide additives.

TECHNOVIEW Organan® Calibrator Set 5x1 mL REF 5090110 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of Organan®* (CAL 1 at 0 IU/mL)
1	Calibrator 2 human plasma, freeze dried, supplemented with Organan®* (CAL 2 at ~ 0.4 IU/mL)
1	Calibrator 3 human plasma, freeze dried, supplemented with Organan®* (CAL 3 at ~ 0.8 IU/mL)
1	Calibrator 4 human plasma, freeze dried, supplemented with Organan®* (CAL 4 at ~ 1.2 IU/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with Organan®* (CAL 5 at ~ 1.6 IU/mL)

TECHNOVIEW Organan® Control Low 5x1 mL REF 5090112 containing 5 vials:

mL	Reagent
1	Control Low human plasma, freeze dried, supplemented with Organan®* (CONT L at ~ 0.50 IU/mL)

TECHNOVIEW Organan® Control High 5x1 mL REF 5090114 containing 5 vials:

mL	Reagent
1	Control High human plasma, freeze dried, supplemented with Organan®* (CONT H at ~ 1.0 IU/mL)

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes
- Distilled water

WARNING AND PRECAUTIONS

- For research use only
- All blood and plasma samples and products have to be regarded as potentially infectious and handled with appropriate care and in compliance with the biosafety regulations in force and must be disposed of in the same way as hospital waste.
- Each single donor plasma and each lot of Control and Calibration plasma are tested and found negative for Hb₂Ag, HIV 1/2 Ab and HCV Ab. However, universal precautions (treating all human source materials as if potentially infectious) should be exercised.

STABILITY AND STORAGE

The expiry date printed on the labels applies to storage of the unopened bottles at +2...8 °C.

Stability after reconstitution:

RT*	+2...8 °C	-20 °C
48 hours	7 days	1 month

The vials can be only frozen once.

Upon storage, caps should be screwed tightly.

*=room temperature ¹

TEST PROCEDURE

PREPARATION AND PERFORMANCE OF THE TEST

- Open the vial carefully and reconstitute the contents in 1 mL of distilled water by carefully rotating the vial until the product is completely reconstituted (avoid frothing).
- Allow the reconstituted TECHNOVIEW Organan® Calibrator and Control plasma to stand for 10 minutes at room temperature before use ¹. Invert to mix before use (avoid foaming).
- Treat the reconstituted plasma as a citrated sample according to the instructions of the respective test.

APPLICATIONS FOR INSTRUMENTS

Application sheets are available from Technoclone or your local distributor upon request.

ANALYSES RESULTS

EVALUATION OF THE RESULTS

The figures in the batch table are only applicable to the indicated lot number of TECHNOVIEW Organan® Calibrator and Control plasma and the method has to adhere strictly as prescribed for the respective reagent.

STANDARDIZATION

TECHNOVIEW Organan® Calibrator and Control plasma are calibrated against an Internal Standard preparation.

LIMITATION OF THE TEST

The figures in the batch table are only applicable to the indicated lot number of TECHNOVIEW Organan® Calibrator and Control plasma and the method has to adhere strictly as prescribed for the respective reagent.

The guidelines for evaluation given in this leaflet have been established assuming that a constant sensitivity of different batches is guaranteed by the manufactures of each reagent.

LITERATURE

1. Magnagni HN. ORGARAN® (Danaparoid sodium) use in the syndrome of heparin-induced thrombocytopenia. Platelets 8: 74-81 (1997).
2. Van Wijk EM et al. A rapid manual chromogenic factor X assay. Thromb Res 25:437- 440 (1982).
3. Leslie B et al. Investigation of the anticoagulant mechanism of a covalent antithrombin-heparin complex. J Biol Chem 52 (273): 34730-34736 (1999).

¹For standardization a reconstitution time of 30 minutes is recommended.

* Organan® is a registered trademark of Schering-Plough.