

Technoview Organan CAL - English

INTENDED USE

Technoview Organan CAL is a set of 5 calibration plasmas to be used for calibration Organan measurements, optimized using Technochrom anti-Xa assay.

SUMMARY

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.

REAGENTS

The Technoview Organan CAL contains:

	Reagent	Description
1 x 1 mL	Technoview Organan CAL 1	Calibrator 1, human plasma, lyophilized, no Organan
1 x 1 mL	Technoview Organan CAL 2	Calibrator 2, human plasma, lyophilized, ~0.4 IU/mL Organan
1 x 1 mL	Technoview Organan CAL 3	Calibrator 3, human plasma, lyophilized, ~0.8 IU/mL Organan
1 x 1 mL	Technoview Organan CAL 4	Calibrator 4, human plasma, lyophilized, ~1.2 IU/mL Organan
1 x 1 mL	Technoview Organan CAL 5	Calibrator 5, human plasma, lyophilized, ~1.6 IU/mL Organan

Please consult the lot specific batch table provided with the controls for the exact concentrations in IU/mL of each calibrator.

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes (1000 µL)
- Laboratory timer
- REF 5340250 Technochrom anti-Xa
- REF 5090112 Technoview Organan CON L
- REF 5090114 Technoview Organan CON H

Warning and precautions

- RUO for research use only.
- This kit is intended for use by personnel trained in laboratory procedures and universal precautions for the use of chemicals and potentially biohazardous substances must be applied.
- All human blood or plasma products as well as test samples must be considered as potentially infectious. They have to be handled with appropriate care and in strict observance of safety regulations. The rules pertaining to disposal are the same as applied to disposing hospital waste.
- Calibrators and control plasmas are made from human blood and any individual plasma involved in the procedure is tested HbsAg, HIV 1/2 Ab and HCV-Ab-negative. However, all human blood products should be handled as potentially infectious material.
- Get a Material Safety Data Sheet for this product from www.technoclone.com.

Stability and storage

The expiry date printed on the labels is only applicable to storage of the unopened containers at 2...8 °C.

Stability opened/ in use:

Reagent	18...25 °C (open vial)	2...8 °C (closed vial)	-20 °C
Technoview Organan CAL 1	48 hours	7 days	1 month
Technoview Organan CAL 2	48 hours	7 days	1 month
Technoview Organan CAL 3	48 hours	7 days	1 month
Technoview Organan CAL 4	48 hours	7 days	1 month
Technoview Organan CAL 5	48 hours	7 days	1 month

Calibrator material can only be frozen once, in its original vial.

TEST PROCEDURE

Preparation of calibrators

Before starting the test, all the required components are to be brought to room temperature.

When reconstituting plasmas, mixing reagents or buffers avoid foaming.

- *Technoview Organan CAL 1 - CAL 5*: Reconstitute each calibrator vial with 1.0 mL of distilled water. Allow the reconstituted material to stand at room temperature for 30 minutes followed by swirling of the vial before use.

Performance of the test

The Technoview Organan CAL is always used in combination with the Technoview Organan CON L and Technoview Organan CON H and the Technochrom anti-Xa kit.

The Organan concentration of calibrator 1 - 5 may vary from one lot to another but is clearly indicated in the lot specific batch table provided in the calibration set.

Calibrator 1, calibrator 2, calibrator 3, calibrator 4 and calibrator 5 are used to establish a calibration curve. Results below the limit of quantification (instrument specific) should be declared as <LoQ. Samples found with a concentration above calibrator 5 should be re-tested in an appropriate dilution.

Technoclone provides instrument specific application sheets, which contain analyser / assay specific handling and performance information.

STANDARDISATION

The Technoview Organan CAL is directly traceable to an internal reference standard.

LITERATURE

Please contact Technoclone www.technoclone.com or your local distributor.

EDITORIAL NOTE

This document is available in several languages. The translations have been done using the master document in English. In the event of doubts or discrepancies, the wording in the master document in English shall take precedence.



Consult instructions for use



Global Trade Item Number



Biological risk



Calibrator

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Manufacturer



Lot



Storage temperature



Research Use Only



Expiry date



Catalogue