

Technoview Edoxaban CAL - English

INTENDED USE

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

SUMMARY

Edoxaban (Savaysa, Lixiana) is an oral anticoagulant drug, which acts as a direct factor Xa inhibitor.

REAGENTS

The Technoview Edoxaban CAL contains:

	Reagent / Content	Description
1 x 1 mL	Technoview Edoxaban CAL 1	Calibrator 1, human plasma, lyophilized no Edoxaban
1 x 1 mL	Technoview Edoxaban CAL 2	Calibrator 2, human plasma, lyophilized, ~50 ng/mL Edoxaban
1 x 1 mL	Technoview Edoxaban CAL 3	Calibrator 3, human plasma, lyophilized, ~140 ng/mL Edoxaban
1 x 1 mL	Technoview Edoxaban CAL 4	Calibrator 4, human plasma, lyophilized, ~300 ng/mL Edoxaban
1 x 1 mL	Technoview Edoxaban CAL 5	Calibrator 5, human plasma, lyophilized, ~500 ng/mL Edoxaban

Please consult the batch table provided with the calibrator set for the exact concentrations in ng/mL of each calibrator.

Material required (not supplied with the kit)

- Distilled water
- Precision pipettes (1000 µL)
- Laboratory timer
-  5340250 Technochrom anti-Xa
-  5090251 Technoview Edoxaban CON L
-  5090252 Technoview Edoxaban CON M
-  5090253 Technoview Edoxaban 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.
- All human blood or plasma products as well as 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
Technoview Edoxaban CAL 1	4 hours
Technoview Edoxaban CAL 2	4 hours
Technoview Edoxaban CAL 3	4 hours
Technoview Edoxaban CAL 4	4 hours
Technoview Edoxaban CAL 5	4 hours

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 Edoxaban 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 Edoxaban CAL is always used in combination with the Technoview Edoxaban CON L, M,H and the Technochrom anti-Xa kit.

The Edoxaban 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.

To cover the whole assay range, two applications are established for this product. For standard application, a calibration curve is established using calibrator 1, calibrator 2 and calibrator 3. All samples are assayed with this application. Results below the limit of quantification (instrument specific) should be declared as <LoQ. Samples found with a concentration above calibrator 3 in standard application should be re-tested using application high. For the application high, calibrator 1, calibrator 3, calibrator 4 and calibrator 5 are used to establish a calibration curve.

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

STANDARDISATION

The Technoview Edoxaban CAL is directly traceable to high performance liquid chromatography with mass spectrometry detection (HPLC-MS).

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.



Expiry date



Catalogue number



Consult instructions for use



Global Trade Item Number



Biological risk



Research use only

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Manufacturer



lot



Storage temperature



Calibrator