

REF	<b>5090251</b>	<b>Technoview Edoxaban CON L</b>	ENG
REF	<b>5090252</b>	<b>Technoview Edoxaban CON M</b>	
REF	<b>5090253</b>	<b>Technoview Edoxaban CON H</b>	
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## Technoview Edoxaban Controls - English

### INTENDED USE

Technoview Edoxaban CON L, CON M and CON H are plasmas with different concentrations of Edoxaban (low, medium and high) to be used for quality control measurements of Edoxaban. They are 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 **REF** 5090251 Technoview Edoxaban CON L contains:

	Reagent	Description
5 x 1 mL	CON L	Human plasma, lyophilized, ~30 ng/mL Edoxaban

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

The **REF** 5090252 Technoview Edoxaban CON M contains:

	Reagent	Description
5 x 1 mL	CON M	Human plasma, lyophilized, ~125 ng/mL Edoxaban

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

The **REF** 5090253 Technoview Edoxaban CON H contains:

	Reagent	Description
5 x 1 mL	CON H	Human plasma, lyophilized, ~400 ng/mL Edoxaban

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

### Material required (not supplied with the kit)

- Distilled water
- Preciso pipettes (1000 µL)
- Laboratory timer
- **REF** 5340250 Technochrom anti-Xa
- **REF** 5090250 Technoview Edoxaban CAL

### 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](http://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	2...8 °C	<-20 °C
Technoview Edoxaban CONT Low	8 hours	6 days	2 weeks
Technoview Edoxaban CONT Medium	8 hours	6 days	2 weeks
Technoview Edoxaban CONT High	8 hours	6 days	2 weeks

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

### TEST PROCEDURE

#### Preparation of controls

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 CON L*: Reconstitute each control 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.
- *Technoview Edoxaban CON M*: Reconstitute each control 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.
- *Technoview Edoxaban CON H*: Reconstitute each control 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 the controls may vary from one lot to another but is clearly indicated in the lot specific batch table provided in the control box.

To cover the whole assay range, two applications are established for this product. For standard application, a quality control using CON L and CON M is recommended. For the application high, a quality control using CON M and CON H is recommended.

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

### STANDARDISATION

The Technoview Edoxaban controls are directly traceable to liquid chromatography with tandem mass spectrometry detection (LC-MS/MS).

### LITERATURE

Please contact Technoclone [www.technoclone.com](http://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.



Manufacturer



Storage temperature



Expiry date



Consult instructions for use



Biological risk

LOT

lot

RUO

Research use only

REF

Catalogue number

GTIN

Global Trade Item Number

CONT

Control

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