REF 5090251	Technoview Edoxaban CON L	ENG
REF 5090252	Technoview Edoxaban CON M	
REF 5090253	Technoview Edoxaban CON H	
3015607RUO Rev.003 03/1	1/2022 RUO	

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		CON L	Human plasma, lyophilized, ~30 ng/mL Edoxaban
D	Please consult the batch table provided with the controls for the exact concentrations in na/ml, of each control		

The REF 5090252 Technoview Edoxaban CON M contains:

ſ		Reagent	Description
Ī	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 cont

The REF 5090253 Technoview Edoxaban CON H contains

		Reagent	Description		
ſ	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 Precisio 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 likes. BUX 1/2 A part MCV Ab perequire. However, all human blood products should be
- 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	1825 °C	28 °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

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

STANDARDISATION

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

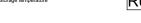
LITERATURE

Please contact Technoclone www.technoclone.com 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.











ung von Diagnostika und Arzneimitteln GmbH, Brunner Str. 67 - 1230 Vienna, Austria Technoview and Technochrom are registered trademarks of Technoclone. Savaysa and Lixiana are registered trademarks of Dailchi Sankyo Company.

Temp. : TF0474.01 Date of printing