

Technoview Apixaban Controls - English

INTENDED USE

Technoview Apixaban CON L and CON H are plasmas with different concentrations of Apixaban (low and high) to be

SUMMARY

Apixaban (Eliquis) is an oral anticoagulant drug, which acts as a direct factor Xa inhibitor.

REAGENTS

The REF 50	The REF 5090271 Technoview Apixaban CON Lcontains:		
	Reagent	Description	
5 x 1 mL	CON L	Human plasma, lyophilized, ~120 ng/mL Apixaban	
Please consult the lot specific batch table provided with the controls for the exact concentrations in ng/mL of each			

The REF 5090270 Technoview Apixaban CON H contains:

	Reagent	Description			
5 x 1 mL	CON H	Human plasma, lyophilized, ~300 ng/mL Apixaban			
Please consult the lot specific 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 Precision pipettes (1000 µL) Laboratory timer
- REF 5340250 Technochrom anti-Xa
 REF 5090269 Technoview Apixaban 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 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 bandled as notentially 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 (open vial)	28 °C (closed vial)
Technoview Apixaban CON L	48 hours	7 days
Technoview Apixaban CON H	48 hours	7 days

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

The Apixaban 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.

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

STANDARDISATION

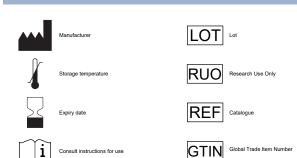
The Technoview Apixaban controls are directly traceable to an internal reference standard.

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.





Herstellung von Diagnostika und Arzneimitteln GmbH, Brunner Str. 67 - 1230 Vienna, Austria Technoview and Technochrom are registered trademarks of Technoclone. Eliquis is a registered trademark of Bristol-Myers Squibb Company.

Temp. : TF0474.01 Date of printing :