

REF	5090172	Technoview Rivaroxaban CON L	ENG
REF	5090173	Technoview Rivaroxaban CON M	
REF	5090174	Technoview Rivaroxaban CON H	
3015208RUO Rev.001 14/07/2021			RUO

Technoview Rivaroxaban Controls - English

INTENDED USE

Technoview Rivaroxaban CON L, CON M and CON H are plasmas with different concentrations of Rivaroxaban (low, medium and high) to be used for quality control measurements of Rivaroxaban. They are optimized using Technochrom anti-Xa assay.

SUMMARY

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

REAGENTS

The REF 5090172 Technoview Rivaroxaban CON L contains:

	Reagent	Description
5 x 1 mL	CON L	Human plasma, lyophilized, ~60 ng/mL Rivaroxaban

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

The REF 5090173 Technoview Rivaroxaban CON M contains:

	Reagent	Description
5 x 1 mL	CON M	Human plasma, lyophilized, ~110 ng/mL Rivaroxaban

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

The REF 5090174 Technoview Rivaroxaban CON H contains:

	Reagent	Description
5 x 1 mL	CON H	Human plasma, lyophilized, ~300 ng/mL Rivaroxaban

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 5090170 Technoview Rivaroxaban CAL
- REF 5090171 Technoview Rivaroxaban CAL 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)
Technoview Rivaroxaban CON L	48 hours	7 days
Technoview Rivaroxaban CON M	48 hours	7 days
Technoview Rivaroxaban 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 Rivaroxaban 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 Rivaroxaban 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 Rivaroxaban 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 Rivaroxaban CAL or the Technoview Rivaroxaban CAL H are always used in combination with the Technoview Rivaroxaban CON L, Technoview Rivaroxaban CON M, Technoview Rivaroxaban CON H and the Technochrom anti-Xa kit.

The Rivaroxaban 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 Rivaroxaban controls are calibrated against liquid-chromatography-tandem mass spectrometry (HPLC-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.



Manufacturer



Storage temperature



Expiry date



Consult instructions for use



Biological risk



Lot



Research Use Only



Catalogue



Global Trade Item Number



Control

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