

REF 5090170	Technoview Rivaroxaban CAL	ENG
REF 5090171	Technoview Rivaroxaban CAL H	
3015178RUO Rev.007 27/06/2021		RUO

Technoview Rivaroxaban Calibrators - English

INTENDED USE

Technoview Rivaroxaban CAL and Technoview Rivaroxaban CAL H are two sets of 5 calibration plasmas to be used for calibration Rivaroxaban measurements, 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 5090170 Technoview Rivaroxaban CAL contains:

	Reagent	Description
1 x 1 mL	Technoview Rivaroxaban CAL 1	Calibrator 1, human plasma, lyophilized, no Rivaroxaban
1 x 1 mL	Technoview Rivaroxaban CAL 2	Calibrator 2, human plasma, lyophilized, ~15 ng/mL Rivaroxaban
1 x 1 mL	Technoview Rivaroxaban CAL 3	Calibrator 3, human plasma, lyophilized, ~60 ng/mL Rivaroxaban
1 x 1 mL	Technoview Rivaroxaban CAL 4	Calibrator 4, human plasma, lyophilized, ~100 ng/mL Rivaroxaban
1 x 1 mL	Technoview Rivaroxaban CAL 5	Calibrator 5, human plasma, lyophilized, ~150 ng/mL Rivaroxaban

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

The REF 5090171 Technoview Rivaroxaban CAL H contains:

	Reagent	Description
1 x 1 mL	Technoview Rivaroxaban CAL 1 H	Calibrator 1 H, human plasma, lyophilized, no Rivaroxaban
1 x 1 mL	Technoview Rivaroxaban CAL 2 H	Calibrator 2 H, human plasma, lyophilized, ~50 ng/mL Rivaroxaban
1 x 1 mL	Technoview Rivaroxaban CAL 3 H	Calibrator 3 H, human plasma, lyophilized, ~100 ng/mL Rivaroxaban
1 x 1 mL	Technoview Rivaroxaban CAL 4 H	Calibrator 4 H, human plasma, lyophilized, ~200 ng/mL Rivaroxaban
1 x 1 mL	Technoview Rivaroxaban CAL 5 H	Calibrator 5 H, human plasma, lyophilized, ~500 ng/mL Rivaroxaban

Please consult the lot specific batch table provided with the controls 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
- REF 5340250 Technochrom anti-Xa
- REF 5090172 Technoview Rivaroxaban CON L
- REF 5090173 Technoview Rivaroxaban CON M
- REF 5090174 Technoview Rivaroxaban 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 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:

REF 5090170 Technoview Rivaroxaban CAL

Reagent	18...25 °C (open vial)	2...8 °C (closed vial)
Technoview Rivaroxaban CAL 1	48 hours	7 days
Technoview Rivaroxaban CAL 2	48 hours	7 days
Technoview Rivaroxaban CAL 3	48 hours	7 days
Technoview Rivaroxaban CAL 4	48 hours	7 days
Technoview Rivaroxaban CAL 5	48 hours	7 days

REF 5090171 Technoview Rivaroxaban CAL H

Reagent	18...25 °C (open vial)	2...8 °C (closed vial)
Technoview Rivaroxaban CAL 1 H	48 hours	7 days
Technoview Rivaroxaban CAL 2 H	48 hours	7 days
Technoview Rivaroxaban CAL 3 H	48 hours	7 days
Technoview Rivaroxaban CAL 4 H	48 hours	7 days
Technoview Rivaroxaban CAL 5 H	48 hours	7 days

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 Rivaroxaban 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.
- *Technoview Rivaroxaban CAL 1 H - CAL 5 H*: 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 Rivaroxaban CAL and the Technoview CAL H are always used in combination with the Technoview Rivaroxaban CON L, Technoview Rivaroxaban CON M and Technoview Rivaroxaban CON H and the Technochrom anti-Xa kit.

The Rivaroxaban concentration of calibrator 1 - 5 and of calibrator 1 - 5 H may vary from one lot to another but is clearly indicated in the lot specific batch table provided in the calibration set.

Calibrator 1, calibrator 2, calibrator 3, calibrator 4 and calibrator 5 respective the calibrator 1 - 5 H are used to establish a calibration curve. Results below the limit of quantification (instrument specific) should be declared as <LoQ. Samples found with a concentration above calibrator 5 or calibrator high 5 should be re-tested in an appropriate dilution.

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

STANDARDISATION











The Technoview Rivaroxaban CAL and the Technoview CAL H 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		Lot
	Storage temperature		Research Use Only
	Expiry date		Catalogue
	Consult instructions for use		Global Trade Item Number
	Biological risk		Calibrator

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