

TECHNOVIEW Rivaroxaban*



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IT






CE

DE

FR

REF	5090170	TECHNOVIEW Rivaroxaban CAL Set	5 x 1 mL
REF	5090171	TECHNOVIEW Rivaroxaban CAL High Set	5 x 1 mL
REF	5090172	TECHNOVIEW Rivaroxaban Low Control	5 x 1 mL
REF	5090173	TECHNOVIEW Rivaroxaban Medium Control	5 x 1 mL
REF	5090174	TECHNOVIEW Rivaroxaban High Control	5 x 1 mL

symbols key / Symbolschlüssel / interpretazione dei simboli / explicación de símbolos / explicação dos símbolos / clé des symboles / Symbolnyckel / symbolforklaring / Tegnforklaring / Κλειδί συμβόλων / Използвани символи / символы / Ključova slova / Značenje simbola

	manufacturer / Hersteller / fabbricante / fabricante / fabricante / fabricant / Tillverkaren / Fabrikanten / Produzent / Κατασκευαστής / Производитель / Производител / vŕyrobce / Proizvodac		expiry date / Verfallsdatum / data di scadenza / fecha de caducidad / data de validade / date d'expiration / utgångsdatum / udløbsdato / Utløpsdato / Ημερομηνία λήξης / срок на годност / datum expirace/ срок годности / datum expirace / Rok trajanja
	storage temperature / Lagertemperatur / temperatura di conservazione / temperatura de conservación / temperatura de conservação / température de stockage / lagringstemperatur / opbevaringstemperatur / Oppbevaringstemperatur / θερμοκρασία αποθήκευσης / съхранение на / teplota skladování / температура хранения / teplota skladování / Temperatura lagerovanja		consult instructions for use / Gebrauchsanweisung beachten / consultare le istruzioni per l'uso / consulte las instrucciones de uso / consultar o manual de instruções / instruction d'utilisation / se användarinstruktioner / følg brugsvejledning / Følg bruksanvisningen / συμβουλευθείτε τις οδηγίες για τη χρήση / прочетете инструкцията за работа / potřeba řídit se instrukcemi / перед использованием читайте инструкцию / sledujte návod k použití / Pročitaj upustvo pre upotrebe
CE	CE-mark / CE-Kennzeichnung / marchio CE / marca de CE / Simbolo da CE / marquage CE / CE-märkning / CE-mærket / CE-merke / CE-σημάδι / CE марка / CE-označení / маркировка CE / značka CE / CE-marka		determinations / Bestimmungen / determinazioni / determinaciones / determinações / déterminations / bestämmingar / bestemmelse / Bestemmelse / προσδιορισμοί / брой тестове / stanovení / определенний / роčet stanovení / Definicija
AQUA	distilled water / destilliertes Wasser / acqua distillata / agua destilada / água destilada / eau distillée / destillerat vatten / destilleret vand / Destillert vann / απεσταγμένο νερό / destilirana voda / destilovaná voda / дистиллированная вода / destilovaná voda / Serija	LOT	lot / Charge / lotto / lote / lote / lot / sats / serie / Parti / партида номер / šarže / lot / šarže / in vitro diagnostika
BUF	Reaction buffer / Reaktionspuffer / tampone di reazione / tampón de reacció / Tampão de reação / tampon de réaction / Reaktionsbuffer / Reaktionsbuffer / Reaktionsbuffer / διάλυμα αντίδρασης / Реакционен буфер / Рабочий буферный раствор / Reakční pufr / Reakcioni pufer	MTP	microtiter plate / Mikrotiterplatte / placa microtiter / microplaca / microplaca / microplaques sensibilisées / Mikrotiterplatta / Mikrotiterplade / mikrotiterplate / πλάκα μικροπλοδότησης / Микротитрна плака / Микропланшет / Mikrotitrační destička / Mikrotitracione ploče
CAL	Calibrator / Kalibrator / Calibratore / calibrador / calibrador / calibreur / Kalibrator / Kalibrator / Kalibrator / Βαθμονομητής / Калибратор / калибратор / kalibrátor / Kalibrator	REF	catalogue number / Katalognummer / numero di catalogo / número de catálogo / número de referência / réf. de catalogue / katalognummer / Katalognummer / αριθμός καταλόγων / каталожный номер / katalogové číslo / каталожный номер / katalogové číslo / Kataloški broj
CONJ	Conjugate / Konjugat / Coniugato / conjugado / conjugado / conjugaté / Konjugerad / Konjugat / Konjugat / συνδεδετικό / Конюгат / Конъюгат / Konjugát / Konjugat	RTU	ready to use / gebrauchsfertig / pronto all'uso / listo para usar / pronto a usar / prêt à l'emploi / færdig att användas / færdig til brug / klar til bruk / έτοιμο προς χρήση / Готов за употреба / готов к использованию / k primému použití / Razrediti ili rastvoriti
CONT	Control / Kontrolle / controllo / control / control / contrôle / Kontroll / Kontroll / Kontroll / διάλυμα ελέγχου / Контроль / Контрольный образец / Kontrola / Kontrola	STOP	stop solution / Stopplösung / Soluzione di arresto / solución de parada / solução de paragem / solution d'arrêt / Stopplösning / Stop-opløsning / Stoppløsning / διάλυμα παύσης / Стоп раствор / Стоп-раствор / Zastavovací roztok / Stop solucija
DIL	dilute or dissolve in / verdünnen oder lösen in / diluire o dissolvere in / diluir o dissolver / diluir ou dissolver em / diluer ou dissoudre dans / späd eller upplös i / fortyndes eller opløses i / Fortyndes eller opløses i / αραιωση ή διάλυση σε / растворяете или разредите с / zředit anebo rozpustit v / разбавить или растворить в / nafedte nebo rozpustit v / razrediti ili rastvoriti u	SUB	substrate / Substrat / substrato / substrato / substrato / substrat / Substrat / Substrat / Substrat / υπόστρωμα / Субстрат / Субстрат / Substrát / Substrat
INC	incubation buffer / Inkubationspuffer / tampone di incubazione / tampón de incubación / tampão de incubação / tampon d'incubation / Inkubationsbuffer/ Inkubationsbuffer/ Vaskebufferkonsentrat / διάλυμα επώασης / Инкубационен буфер / Буфер для инкубации / Inkubační pufr / Inkubacioni pufer	WASH	washing solution concentrate / Waschlösungskonzentrat / concentrado de solución de lavado / solución de lavado concentrada / tampão de lavagem concentrado / Tampon de lavage concentré / Vattenlösningkoncentrat / Vaskeopløsningskoncentrat / vaskeløsningskonsentrat / συμπυκνωμένο διάλυμα πλύσης / Концентриран миеш раствор / Концентрат промывочного раствора / Koncentrát promývacieho roztoku / Koncentrat solucije za ispiranje
RUO	in vitro research use only		



TECHNOVIEW Rivaroxaban*

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PRODUCT DESCRIPTION

INTENDED USE – RESEARCH USE ONLY

TECHNOVIEW Rivaroxaban Calibrator Set is a set of calibration plasmas and TECHNOVIEW Rivaroxaban Control Plasma is a set of low, medium and high control plasmas to be used for calibration and the quality control of rivaroxaban measurements, optimised using anti-Xa assays.

COMPOSITION

TECHNOVIEW Rivaroxaban Calibrator and Control plasma are prepared from citrated plasmas supplemented with different concentrations of rivaroxaban*. The plasma contains stabilizers but no bactericide additives.

TECHNOVIEW Rivaroxaban Calibrator Set 5x1 mL REF 5090170 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of rivaroxaban (CAL 1 at 0 ng/mL)
1	Calibrator 2 human plasma, freeze dried, supplemented with rivaroxaban (CAL 2 at ~ 15 ng/mL)
1	Calibrator 3 human plasma, freeze dried, supplemented with rivaroxaban (CAL 3 at ~ 60 ng/mL)
1	Calibrator 4 human plasma, freeze dried, supplemented with rivaroxaban (CAL 4 at ~ 100 ng/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with rivaroxaban (CAL 5 at ~ 150 ng/mL)

TECHNOVIEW Rivaroxaban Calibrator Set High 5x1 mL REF 5090171 contains:

mL	Reagent
1	Calibrator 1 high human plasma, freeze dried, without any additive of rivaroxaban (CAL 1 at 0 ng/mL)
1	Calibrator 2 high human plasma, freeze dried, supplemented with rivaroxaban (CAL 2 at ~50 ng/mL)
1	Calibrator 3 high human plasma, freeze dried, supplemented with rivaroxaban (CAL 3 at ~100 ng/mL)
1	Calibrator 4 high human plasma, freeze dried, supplemented with rivaroxaban (CAL 4 at ~ 200 ng/mL)
1	Calibrator 5 high human plasma, freeze dried, supplemented with rivaroxaban (CAL 5 at ~ 500 ng/mL)

TECHNOVIEW Rivaroxaban Control Low 5x1 mL REF 5090172 containing 5 vials:

mL	Reagent
1	Control Low human plasma, freeze dried, supplemented with rivaroxaban (CONT L at ~ 60 ng/mL)

TECHNOVIEW Rivaroxaban Control Medium 5x1 mL REF 5090173 containing 5 vials:

mL	Reagent
1	Control Medium human plasma, freeze dried, supplemented with rivaroxaban (CONT M at ~ 110 ng/mL)

TECHNOVIEW Rivaroxaban Control High 5x1 mL REF 5090174 containing 5 vials:

mL	Reagent
1	Control High human plasma, freeze dried, supplemented with rivaroxaban (CONT H at ~ 300 ng/mL)

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes
- Distilled water

WARNING AND PRECAUTIONS

- RUO for *in vitro* research use only
- All blood and plasma samples and products have to be regarded as potentially infectious and handled with appropriate care and in compliance with the biosafety regulations in force and must be disposed of in the same way as hospital waste.
- Each single donor plasma and each lot of Control and Calibration plasma are tested and found negative for Hb_sAg, HIV 1/2 Ab and HCV Ab. However, universal precautions (treating all human source materials as if potentially infectious) should be exercised.

STABILITY AND STORAGE

The expiry date printed on the labels applies to storage of the unopened bottles at +2...8 °C.

Stability after reconstitution:

RT*	+2...8 °C
48 hours	7 days

Upon storage, caps should be screwed tightly.

*=room temperature

TEST PROCEDURE

PREPARATION AND PERFORMANCE OF THE TEST

- Open the vial carefully and reconstitute the contents in **1 mL of distilled water** by carefully rotating the vial until the product is completely reconstituted (avoid foaming).
- Allow the reconstituted TECHNOVIEW Rivaroxaban Calibrator and Control plasma to stand for at least 10 minutes at room temperature before use. Invert to mix before use (avoid foaming).
- Treat the reconstituted plasma as a citrated patient sample according to the instructions of the respective test.
- TECHNOVIEW Rivaroxaban Calibrator plasmas allow the calibration of anti-Xa assays for the measurement of rivaroxaban* in plasma.

APPLICATIONS FOR INSTRUMENTS

Application sheets are available from Technoclone or your local distributor upon request.

ANALYSES RESULTS

EVALUATION OF THE RESULTS

The figures in the batch table are only applicable to the indicated lot number of TECHNOVIEW Rivaroxaban Calibrator and Control plasma and the method has to adhere strictly as prescribed for the respective reagent.

STANDARDIZATION

TECHNOVIEW Rivaroxaban Calibrator and Control plasma are calibrated against according to rivaroxaban standard method (3).

LIMITATION OF THE TEST

The figures in the batch table are only applicable to the indicated lot number of TECHNOVIEW Rivaroxaban Calibrator and Control plasma and the method has to adhere strictly as prescribed for the respective reagent.

Two step anti-Xa assays with addition of antithrombin are not suitable for measurement of rivaroxaban.

PERFORMANCE CHARACTERISTICS

TECHNOVIEW Rivaroxaban Control plasmas allow the validation of the calibration curve for the measurements of rivaroxaban* in plasma, especially with anti-Xa methods. The calibration curves covers a range from 0-500ng/mL. For concentrations <150ng/mL a calibration curve in the range 0-150ng/mL should be used and concentrations >150ng/mL should be reassayed with the settings for calibration range 0-500ng/mL.

Attention!! Results below detection limit of the used anti-Xa assay should be declared as < LOD

LITERATURE

1. Arterioscler Thromb Vasc Biol. 2010;30:376-381. Perzborn. Rivaroxaban: A New Oral Factor Xa Inhibitor
2. Ther Drug Monit 2010. Lindhoff-Last. Assays for Measuring Rivaroxaban: Their Suitability and Limitations
3. Journal of Chromatography B. 872 (2008) 43–50. g. Rohde. Determination of rivaroxaban – a novel, oral, direct Factor Xa inhibitor – in human plasma by high-performance liquid chromatography–tandem mass spectrometry

* For standardization a reconstitution time of 30 minutes is recommended.

* Rivaroxaban is the active substance in Xarelto® which is a registered trade mark of Bayer