

TECHNOVIEW Apixaban*



GB

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CE

DE

FR

REF	5090269	TECHNOVIEW Apixaban CAL Set	5 x 1 mL
REF	5090270	TECHNOVIEW Apixaban High Control	5 x 1 mL
REF	5090271	TECHNOVIEW Apixaban Low 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 / Tilverkaren / Fabrikanten / Produzent / Κατασκευαστής / Производитель / Производител / výrobce / Proizvođač		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 / potfeba fidiť 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 / bestemmelser / Bestemmelser / προσδιορισμοί / брой тестове / stanovení / определный / роčet stanovení / Definicija
AQUA	distilled water / destilliertes Wasser / acqua distillata / agua destilada / água destilada / eau distillée / destillerat vatten / destilleret vand / Destillert vann / απεσταγμένο νερό / дестилирана вода / destilovaná voda / дистиллированная вода / destilovaná voda / Serija	LOT	lot / Charge / lotto / lote / lote / lot / sats / serie / Parti / партиа / партида номер / šarže / лот / šarže / in vitro dijagnostika
BUF	Reaction buffer / Reaktionspuffer / tampone di reazione / tampón de reacció / Tampão de reação / tampon de réaction / Reaktionsbuffert / Reaktionsbuffer / Reaksjonsbuffer / διάλυμα αντίδρασης / Реакцион буфер / Рабочий буферный раствор / Reakčni pufr / Reakcioni pufer	MTP	microtiter plate / Mikrotiterplatte / placa microtiter / microplaca / microplaca / microplaques sensibiliées / Mikrotiterplatta / Mikrotiterplade / mikrotiterplate / πλάκα μικροτιτλοδότησης / Микротитърна плака / Микропланшет / Mikrotitracijska 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 / καταλογен 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 přímému použití / Razrediti ili rastvoriti
CONT	Control / Kontrolle / controllo / control / control / contrôle / Kontroll / Kontroll / Kontroll / διάλυμα ελέγχου / Контрол / Контрольный образец / Kontrola / Kontrola	STOP	stop solution / Stoppløsning / Soluzione di arresto / solución de parada / solução de paragem / solution d'arrêt / Stoppløsning / Stop-opløsning / Stoppløsning / διάλυμα παύσης / Стоп разтвор / Стоп-раствор / Zastavovací roztok / Stop solucija
DIL	dilute or dissolve in / verdünnen oder lösen in / diluire o dissolvere in / diluir o disolver / diluir ou dissolver em / diluer ou dissoudre dans / späd eller upplös i / fortyndes eller opløses i / Fortyndes eller opløses i / αραιωση ή διάλυση σε / разтворете или разрежете 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 / Vattenlösningsskoncentrat / Vaskeopløsningskoncentrat / vaskeløsningskoncentrat / συμπυκνωμένο διάλυμα πλύσης / Концентриран миеш разтвор / Концентрат промывочного раствора / Koncentrat promývacieho roztoku / Koncetrat solucije za ispiranje
RUO	in vitro research use only		Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH Brunner Str. 67 - 1230 Vienna, Austria

PRODUCT DESCRIPTION

INTENDED USE – RESEARCH USE ONLY

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

COMPOSITION

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

TECHNOVIEW Apixaban Calibrator Set 5x1 mL [REF] 5090269 contains:

mL	Reagent
1	Cal. 1 high human plasma, freeze dried, without any additive of apixaban (~ 0 ng/mL)
1	Cal. 2 high human plasma, freeze dried, supplemented with apixaban (~50 ng/mL)
1	Cal. 3 high human plasma, freeze dried, supplemented with apixaban (~180 ng/mL)
1	Cal. 4 high human plasma, freeze dried, supplemented with apixaban (~ 350 ng/mL)
1	Cal. 5 high human plasma, freeze dried, supplemented with apixaban (~ 500 ng/mL)

TECHNOVIEW Apixaban Control High 5x1 mL [REF] 5090270 containing 5 vials:

mL	Reagent
1	Cont. High human plasma, freeze dried, supplemented with apixaban (~ 300 ng/mL)

TECHNOVIEW Apixaban Control Low 5x1 mL [REF] 5090271 containing 5 vials:

mL	Reagent
1	Cont. Low human plasma, freeze dried, supplemented with apixaban (~ 120 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.
temperature

*=room

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 (avoid foaming).
- Allow the reconstituted TECHNOVIEW Apixaban Calibrator and Control plasma to stand for at least 10 minutes at room temperature before use. For standardization a reconstitution time of 30 minutes is recommended.
- Treat the reconstituted plasma as a citrated patient sample according to the instructions of the respective test.
- TECHNOVIEW Apixaban Calibrator plasmas allow the calibration of anti-Xa assays for the measurement of apixaban* 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 Apixaban Calibrator and Control plasma and the method has to adhere strictly as prescribed for the respective reagent.

STANDARDIZATION AND TRACEABILITY

Using an anti Xa assay TECHNOVIEW Apixaban Calibrator and Control plasma are calibrated in ng/mL against an internal reference standard and in IU/ against the international standard for LMW in plasma.

LIMITATION OF THE TEST

The figures in the batch table are only applicable to the indicated lot number of TECHNOVIEW Apixaban 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 apixaban.

PERFORMANCE CHARACTERISTICS

TECHNOVIEW Apixaban Control plasmas allow the validation of the calibration curve for the measurements of apixaban* in plasma, especially with anti-Xa methods. The calibration curve covers a range from 0-500ng/mL.

LITERATURE

Please contact Technoclone or your local distributor.

* Apixaban is the active substance in Eliquis which is a registered trade mark of BMS.