

TECHNOVIEW Arixtra®*



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RU

REF	5090010	TECHNOVIEW Arixtra® CAL Set	5 x 1 mL
REF	5090011	TECHNOVIEW Arixtra® CAL Kit	2 x 1 mL
REF	5090012	TECHNOVIEW Arixtra® CONT Low	6 x 1 mL
REF	5090014	TECHNOVIEW Arixtra® CONT High	6 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 / fabricant / Tillverkaren / Fabrikanten / Produzent / Κατασκευαστής / Производитель / Производител / výrobc / Proizvodač		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 lagerovnja		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 / определний / počet stanovení / Definicija
AQUA	distilled water / destilliertes Wasser / acqua distillata / agua destilada / água destilada / eau distillée / destillerat vatten / destilleret vand / Destillert vann / απεσταγμένο νερό / децтилана вода / destilovaná voda / дистиллированная вода / destilovaná voda / Serija	LOT	lot / Charge / lotto / lote / lote / lot / sats / serie / Parti / ηαρία / партида номер / šarže / лот / šarže / in vitro dijagnostika
BUF	Reaction buffer / Reaktionspuffer / tampone di reazione / tampón de reacció / Tampão de reação / tampon de réaction / Reaktionspuffer / Reaktionsbuffer / Реаксионсбуфер / 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 μικροτιτλοδότησης / Микротитрна плака / Микропланшет / Mikrotitračni 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 / каталожен 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 / Stopplösning / Soluzione di arresto / solución de parada / solução de paragem / solution d'arrêt / Stoppløsning / 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 / растворите или разреждете с / zředí anebo rozpustit v / разбавить или растворить в / nafedte nebo rozpustite 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 / Vaskeoplosningskonsentrat / vaskeløsningskonsentrat / συμπυκνωμένο διάλυμα πλύσης / Концентриран миещ разтвор / Концентрат промывочного раствора / Koncentrat promývacieho roztoku / Koncetrat solucije za ispiranje
RUO	in vitro research use only		



PRODUCT DESCRIPTION

INTENDED USE – RESEARCH USE ONLY

TECHNOVIEW Arixtra Calibrator Set is a set of calibration plasmas and TECHNOVIEW Arixtra Control Plasma is a set of low and high control plasmas for calibration and the quality control of Arixtra (Fondaparinux sodium) measurements, titrated and optimised using anti-Xa assays.

Arixtra® can be used as an anticoagulant for curative or preventive indications. Measuring the Arixtra concentration in patient's plasma allows monitoring the therapy and adjusting drug dosage.

COMPOSITION

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

TECHNOVIEW Arixtra Calibrator Set 5x1 mL [REF] 5090010 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of Arixtra (CAL 1 at 0 µg/mL)
1	Calibrator 2 human plasma, freeze dried, supplemented with Arixtra (CAL 2 at ~ 0.5 µg/mL)
1	Calibrator 3 human plasma, freeze dried, supplemented with Arixtra (CAL 3 at ~ 1 µg/mL)
1	Calibrator 4 human plasma, freeze dried, supplemented with Arixtra (CAL 4 at ~ 1.5 µg/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with Arixtra (CAL 5 at ~ 2 µg/mL)

TECHNOVIEW Arixtra Calibrator Kit 2x1 mL [REF] 5090011 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of Arixtra (CAL 1 at 0 µg/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with Arixtra (CAL 5 at ~ 2 µg/mL)

TECHNOVIEW Arixtra Control Low 6x1 mL [REF] 5090012 containing 6 vials:

mL	Reagent
1	Control Low human plasma, freeze dried, supplemented with Arixtra (CONT L at ~ 0.4 µg/mL)

TECHNOVIEW Arixtra Control High 6x1 mL [REF] 5090014 containing 6 vials:

mL	Reagent
1	Control High human plasma, freeze dried, supplemented with Arixtra (CONT H at ~ 1.2 µg/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	-20 °C
48 hours	7 days	1 month

The vials can be only frozen once. Upon storage, caps should be screwed tightly.

*=room temperature¹

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 frothing).
- Allow the reconstituted TECHNOVIEW Arixtra Calibrator and Control plasma to stand for 10 minutes at room temperature before use¹. Invert to mix before use (avoid foaming).
- Treat the reconstituted plasma as a citrated patient sample according to the instructions of the respective test.

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 Arixtra Calibrator and Control plasma and the method has to adhere strictly as prescribed for the respective reagent.

STANDARDIZATION

TECHNOVIEW Arixtra Calibrator and Control plasma are calibrated against the International Standard preparation 01/608.

LIMITATION OF THE TEST

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

The guidelines for evaluation given in this leaflet have been established assuming that a constant sensitivity of different batches is guaranteed by the manufactures of each reagent.

PERFORMANCE CHARACTERISTICS

TECHNOVIEW Arixtra Control plasmas allow validating the calibration curve for the measurements of Arixtra®* in plasma, especially with anti-Xa methods. The calibration curve obtained covers the usual concentrations currently observed during Arixtra®* therapy. The currently available anti-Xa methods, used for the measurement of heparins and their analogues in plasma, offer a sensitivity threshold of about 0.05 µg/mL.

LITERATURE

1. J. Hirsch, "Fondaparinux", BC Decker Inc., Hamilton, 2007.
 2. J.M. Walenga, J. Fareed, W.P. Jeske, F.X. Frapaise, R.L. Bick, M.M. Samama, "Development of a Synthetic Heparin Pentasaccharide: Fondaparinux", *Turk J Haematol*, 2002; 19(2):137-150.

¹ For standardization a reconstitution time of 30 minutes is recommended.

* Arixtra® is a registered trade mark of Glaxo Smith Kline