









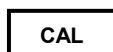

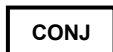



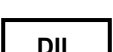
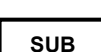


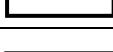


TECHNOVIEW LMW



REF	5090040	TECHNOVIEW LMW CAL Set	5 x 1 mL
REF	5090041	TECHNOVIEW LMW CAL Kit	2 x 1 mL
REF	5090042	TECHNOVIEW LMW CONT Low	5 x 1 mL
REF	5090044	TECHNOVIEW LMW CONT Medium	5 x 1 mL
REF	5090046	TECHNOVIEW LMW CONT High	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 / Produsent / Κατασκευαστής / Производитель / Производител / výrobc / 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 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-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 / определний / роčet stanovení / Definicija
	distilled water / destilliertes Wasser / acqua distillata / agua destilada / água destilada / eau distillée / destillerat vatten / destilleret vand / Destillert vann / απεσταγμένο νερό / дестилирана вода / destilovaná voda / дистилюванна вода / destilovaná voda / Serija		lot / Charge / lotto / lote / lote / lot / sats / serie / Parti / парти / партида номер / šarže / лот / šarže / in vitro diagnostika
	Reaction buffer / Reaktionspuffer / tampone di reazione / tampón de reacció / Tampão de reação / tampon de réaction / Reaktionsbuffert / Reaktionsbuffer / Reaksjonsbuffer / διάλυμα αντίδρασης / Реакционен буфер / Рабочий буферный раствор / Reakčni pufr / Reakcioni pufer		microtiter plate / Mikrotiterplatte / placa microtiter / microplaca / microplaca / microplaques sensibilisées / Mikrotiterplatta / Mikrotiterplade / mikrotiterplate / πλάκα μικροπλοδότησης / Микротитърна плака / Микропланшет / Mikrotitrační destička / Mikrotitracione ploče
	Calibrator / Kalibrator / Calibratore / calibrador / calibrador / calibreur / Kalibrator / Kalibrator / Kalibrator / Βαθμονομητής / Калибратор / калибратор / kalibrátor / Kalibrator		catalogue number / Katalognummer / numero di catalogo / número de catálogo / número de referência / réf. de catalogue / katalognummer / Katalognummer / αριθμός καταλόγων / καταложен номер / katalogové číslo / каталожный номер / katalogové číslo / Kataloški broj
	Conjugate / Konjugat / Coniugato / conjugado / conjugado / conjugaté / Konjugerad / Konjugat / Konjugat / συνδεδετικό / Конюгат / Конъюгат / Konjugát / Konjugat		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
	Control / Kontrolle / controllo / control / control / contrôle / Kontroll / Kontroll / Kontroll / διάλυμα ελέγχου / Контрол / Контрольный образец / Kontrola / Kontrola		stop solution / Stopplösung / 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
	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 разредете с / zřediti anebo rozpustit v / разбавить или растворить в / naředite nebo rozpusťte v / razrediti ili rastvoriti u		substrate / Substrat / substrato / substrato / substrato / substrat / Substrat / Substrat / Substrat / υπόστρωμα / Субстрат / Субстрат / Substrát / Substrat
	incubation buffer / Inkubationspuffer / tampone di incubazione / tampón de incubación / tampão de incubação / tampon d'incubation / Inkubationsbuffert / Inkubationsbuffer / Vaskebufferkonsentrat / διάλυμα επώασης / Инкубационен буфер / Буфер для инкубации / Inkubační pufr / Inkubacioni pufer		washing solution concentrate / Waschlösungskonzentrat / concentrado de solución de lavado / solución de lavado concentrada / tampão de lavagem concentrado / Tampon de lavage concentré / Vattenlösningsskoncentrat / Vaskeoppløsningskonsentrat / vaskeløsningskonsentrat / συμπικνωμένο διάλυμα πλύσης / Концентриран миеш разтвор / Концентрат промывочного раствора / Koncentrát promývacího roztoku / Koncetrat solucije za ispiranje
	in vitro research use only		



PRODUCT DESCRIPTION**INTENDED USE – RESEARCH USE ONLY**

TECHNOVIEW LMW Calibrator Set is a set of calibration plasmas and TECHNOVIEW LMW Control Plasma is a set of low, medium and high control plasmas for calibration and the quality control of Low Molecular Weight (LMW) Heparin measurements titrated and optimised using anti-Xa assays. Heparin is the most frequently used antithrombotic therapeutic drug. The biological activity of this sulfated glycosaminoglycan resides in its ability to accelerate (up to 2000-fold) the inhibitory effect of antithrombin (AT) on the coagulation proteases.

COMPOSITION

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

TECHNOVIEW LMW Calibrator Set 5x1 mL [REF] 5090040 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of LMW Heparin (CAL 1 at 0 IU/mL)
1	Calibrator 2 human plasma, freeze dried, supplemented with LMW Heparin (CAL 2 at ~ 0.4 IU/mL)
1	Calibrator 3 human plasma, freeze dried, supplemented with LMW Heparin (CAL 3 at ~ 0.8 IU/mL)
1	Calibrator 4 human plasma, freeze dried, supplemented with LMW Heparin (CAL 4 at ~ 1.2 IU/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with LMW Heparin (CAL 5 at ~ 1.6 IU/mL)

TECHNOVIEW LMW Calibrator Kit 2x1 mL [REF] 5090041 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of LMW Heparin (CAL 1 at 0 IU/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with LMW Heparin (CAL 5 at ~ 1.6 IU/mL)

TECHNOVIEW LMW Control Low 5x1 mL [REF] 5090042 containing 5 vials:

mL	Reagent
1	Control Low human plasma, freeze dried, supplemented with LMW Heparin (CONT L at ~ 0.35 IU/mL)

TECHNOVIEW LMW Control Medium 5x1 mL [REF] 5090044 containing 5 vials:

mL	Reagent
1	Control Medium human plasma, freeze dried, supplemented with LMW Heparin (CONT M at ~ 0.7 IU/mL)

TECHNOVIEW LMW Control High 5x1 mL [REF] 5090046 containing 5 vials:

mL	Reagent
1	Control High human plasma, freeze dried, supplemented with LMW Heparin (CONT H at ~ 1.1 IU/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 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 frothing).
- Allow the reconstituted TECHNOVIEW LMW Heparin Calibrator and Control plasma to stand for 10 minutes at room temperature before use ¹. 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 LMW Calibrator and Control plasma and the method has to adhere strictly as prescribed for the respective reagent.

STANDARDIZATION

TECHNOVIEW LMW 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 LMW 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 LMWH Control plasmas allow validating the calibration curve for the measurements of Low Molecular Weight Heparin (LMWH) in plasma, especially with anti-Xa methods. The calibration curve obtained covers the usual concentrations currently observed during Low Molecular Weight Heparin (LMWH) 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 IU/mL.

LITERATURE

- Richardson J.H. and Backley W.E. Eds. Bios. Microbiological and Biomedical laboratories. US. Dept. and Human Services. Public Health Service, HHS publication (CDC) 84-8395, Washington, D.C. (1984).
- National Committee for Clinical Laboratory St Specifications for reagent water used in the clinical lab NCCLS Approved Standard: ASC-3.
- Westgard J.O., Barry P.L. Cost effective Quality Managing for managing the quality and the Productivity of Analytical AACC Press (1986).

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