





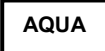

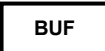

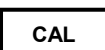

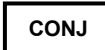
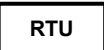




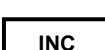

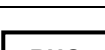


TECHNOVIEW UFH



REF	5090070	TECHNOVIEW UFH CAL Set	5 x 1 mL
REF	5090071	TECHNOVIEW UFH CAL Kit	2 x 1 mL
REF	5090072	TECHNOVIEW UFH CONT L	5 x 1 mL
REF	5090074	TECHNOVIEW UFH CONT H	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 / 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 / oppbevaringstemperatur / Oppbevaringstemperatur / Вреќокрасја опшћекушјс / 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 bruksveiledning / Følg bruksanvisningen / συμβουλευθείτε τις οδηγίες για τη χρήση / прочетете инструкцията за работа / potřeba fidiť 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 / destilirana voda / destilovaná voda / дистиллированная вода / destilovaná voda / Serija		lot / Charge / lotto / lote / lote / lot / sats / serie / Parti / партида номер / šarže / лот / šarže / in vitro dijagnostika
	Reaction buffer / Reaktionspuffer / tampone di reazione / tampón de reacció / Tampão de reação / tampon de réaction / Reaktionsbuffer / Reaktionsbuffer / Reaksjonsbuffer / διάλυμα αντίδρασης / Реакционен буфер / Рабочий буферный раствор / Reakční pufr / Reakcioni pufer		microtiter plate / Mikrotiterplatte / placa microtiter / microplaca / microplaca / microplaques sensibilisées / Mikrotiterplatta / Mikrotiterplade / mikrotiterplate / πλάκα μικροτιτλοδότησης / Микротитърна плака / Микропланшет / Mikrotitració 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 / каталожен 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 / spädd eller upplös i / fortyndes eller opløses i / Fortyndes eller opløses i / αραιωση ή διάλυση σε / разтворете или разреждете с / zředit anebo rozpuštět v / разбавить или растворить в / nafedte nebo rozpustit 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 / Inkubationsbuffer / 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 / Vattenlösningkoncentrat / Vaskeopløsningskoncentrat / vaskeløsningskoncentrat / συμπυκνωμένο διάλυμα πλύσης / Концентриран миеш разтвор / Концентрат промывочного раствора / Koncentrát promývacieho roztoku / Koncetrat solucije za ispiranje
	in vitro research use only		



PRODUCT DESCRIPTION

INTENDED USE – RESEARCH USE ONLY

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

COMPOSITION

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

TECHNOVIEW UFH Calibrator Set 5x1 mL REF 5090070 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of UFH (CAL 1 at 0 IU/mL)
1	Calibrator 2 human plasma, freeze dried, supplemented with UFH (CAL 2 at ~ 0.35 IU/mL)
1	Calibrator 3 human plasma, freeze dried, supplemented with UFH (CAL 3 at ~ 0.70 IU/mL)
1	Calibrator 4 human plasma, freeze dried, supplemented with UFH (CAL 4 at ~ 1.05 IU/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with UFH (CAL 5 at ~ 1.40 IU/mL)

TECHNOVIEW UFH Calibrator Kit 2x1 mL REF 5090071 contains:

mL	Reagent
1	Calibrator 1 human plasma, freeze dried, without any additive of UFH (CAL 1 at 0 IU/mL)
1	Calibrator 5 human plasma, freeze dried, supplemented with UFH (CAL 5 at ~ 1.40 IU/mL)

TECHNOVIEW UFH Control Low 5x1 mL REF 5090072 containing 5 vials:

mL	Reagent
1	Control Low human plasma, freeze dried, supplemented with UFH (CONT L at ~ 0.20 IU/mL)

TECHNOVIEW UFH Control High 5x1 mL REF 5090074 containing 5 vials:

mL	Reagent
1	Control High human plasma, freeze dried, supplemented with UFH (CONT H at ~ 0.50 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 ¹

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

STANDARDIZATION

TECHNOVIEW UFH Calibrator and Control plasma are calibrated against the 5th International Standard preparation for UFH 97/578.

LIMITATION OF THE TEST

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

LITERATURE

1. 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).
2. National Committee for Clinical Laboratory St Specifications for reagent water used in the clinical lab NCCLS Approved Standard: ASC-3.
3. Westgard J.O., Barry P.L. Cost effective Quality Managing for managing the quality and the Productivity of Analytical AACC Press (1986).

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

