

TECHNOCLOT[®] DTI







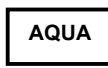



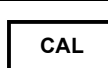

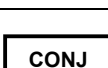

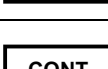
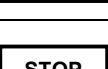
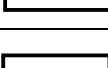
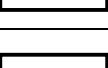
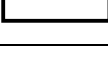
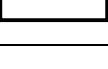
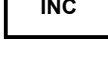




REF 5100025 TECHNOCLOT DTI

2 x 20 T.

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 / Производител / 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 řidit 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 / bestämningar / bestemmelse / Bestemmelse / προσδιορισμοί / брой тестове / stanovení / определний / počet stanovení / Definicija
	distilled water / destilliertes Wasser / acqua distillata / agua destilada / água destilada / eau distillée / destillerat vatten / destilleret vand / Destillert vann / απεσταγμένο νερό / децилирана вода / destilovaná voda / дистиллированная 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 / Реакční pufr / Reakcioni pufer		microtiter plate / Mikrotiterplatte / placa microtiter / microplaca / microplaca / microplaques sensibilisées / Mikrotiterplatta / Mikrotiterplade / mikrotiterplate / πλάκα μικροτιτλοδότησης / 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 / καταλογен 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 раствор / 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 oppløs i / fortyndes eller opløses i / Fortyndes eller opløses i / αραιωση ή διάλυση σε / растворете или разредете с / zředit anebo rozpusťit v / разбавить или растворить в / naředte nebo rozpustte 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 / incubação / 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 / Vattenlösningskoncentrat / Vaskeoppløsningskoncentrat / vaskeoppløsningskoncentrat / συμπυκνωμένο διάλυμα πλύσης / Концентриран миелс раствор / Концентрат промывочного раствора / Koncentrát promývacieho roztoku / Koncentrat solucije za ispiranje
	in vitro diagnostic use / in vitro Diagnostikum / diagnostico in vitro / diagnóstico en vitro / diagnóstico in vitro / diagnostic in vitro / för in vitro diagnostik / in vitro diagnostik / in vitro diagnostisk bruk / рηση διαγνωστικής εντόβ σωλήνα / за ин vitro диагностика / pro in vitro diagnostiku / использовать для диагностики in vitro / diagnostický prostředek in vitro / Destilísana Voda		



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PRODUCT DESCRIPTION

INTENDED USE

TECHNOCLOT® DTI is used for the determination of anticoagulant activity of the direct thrombin inhibitor (DTI) Dabigatran in human citrated plasma. Dabigatran is the active component of the oral anticoagulant pro-drug, Dabigatran Etxilate which has been approved for various applications under the tradename Pradaxa®.

To measure Dabigatran in plasma, the diluted patient sample is mixed with normal human plasma (R1). Clotting is then initiated by adding the thrombin reagent (R2). The clotting time measured is directly related to the concentration of the Dabigatran in the sample plasma.

COMPOSITION

vial	Reagents
2 x 2mL	Reagent 1 (R1): Normal Plasma, lyophilized
2 x 2mL	Reagent 2 (R2): Bovine Thrombin, stabilizer, polybrene, lyophilized

MATERIAL REQUIRED (not supplied with the kit)

- Pipette: 200 µL
- Distilled water
- Diluent, Sodium Chloride solution 0.9%
- Calibration plasma

[REF] 5090210 TECHNOVIEW® Dabigatran Calibrators 1-4 4 x 1 mL

- Control plasma

[REF] 5090214 TECHNOVIEW® Dabigatran Control Low 5 x 1 mL

[REF] 5090212 TECHNOVIEW® Dabigatran Control High 5 x 1 mL

WARNING AND PRECAUTIONS

- IVD for *in vitro* diagnostic use
- 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.

STABILITY AND STORAGE

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

Stability after reconstitution:

--- R1 & R2 ---	--- RT* --- 8 hours	--- -20°C --- 1 month
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*=room temperature

The vials can be frozen up to two freeze/thaw cycles. Upon storage, caps should be screwed tightly

TEST PROCEDURE

PREPARATION OF PLASMA SAMPLES

Plasma separation:
Mix 9 parts of venous blood and 1 part of Sodium Citrate Solution (0.11 mol/L) and centrifuge for 15 min at a RCF of at least 2500 g (corresponding to DIN 58905). Store the plasma at room temperature.

PREPARATION OF REAGENT

Carefully open the vial and reconstitute the lyophilised reagent in the volume of distilled water indicated on the vial label. Slowly rotate the vial. Allow the reconstituted reagent to stand for 10 minutes at room temperature. For standardisation a reconstitution time of 30 min is recommended.

PERFORMANCE OF THE TEST

CEVERON® ALPHA AND OTHER ANALYZERS

Technoclone provides application sheets for Ceveron® alpha. The application sheets contain analyzer/assay specific handling and performance information, which may differ from that provided in this instruction for use. In this case the information contained in the application sheet supersedes the information in this instruction for use. Please consult the instruction manual of the Ceveron® alpha. Application sheets for other analyzers are available on request.

MANUAL

The assay is calibrated with the Dabigatran Calibrators. Calibrators, controls and patient samples are diluted 1:8 with 0.9% sodium chloride solution.

Pipetting scheme:

0.05 mL diluted calibrator, control, patient plasma (room temperature)
+ 0.10 mL TECHNOCLOT® DTI Reagent 1 (room temperature)
Incubate for 2 minutes at 37°C
+ 0.10 mL TECHNOCLOT® DTI Reagent 2 (room temperature)
determine the point of coagulation

LIMITATION OF THE TEST

The values found when testing control plasma should be compared to the value given on the control batch table for the corresponding lot of Control plasma. If the results obtained are outside the recommended range, avoid measuring patient samples until the problem is solved.

Blood activation, during specimen collection and plasma preparation, may interfere in the assay. No significant interference of excess or deficiency of other plasma factors was identified in compliance with the test principle using diluted test plasma and a substrate plasma in excess. However special caution is recommended for plasmas presenting a constitutional or acquired hypocoagulability. In order to get the optimal assay performances, the working instructions must be carefully followed. Incubation times indicated have to be followed strictly.

ANALYSES OF RESULTS

EVALUATION USING A REFERENCE CURVE (example using Ceveron®)

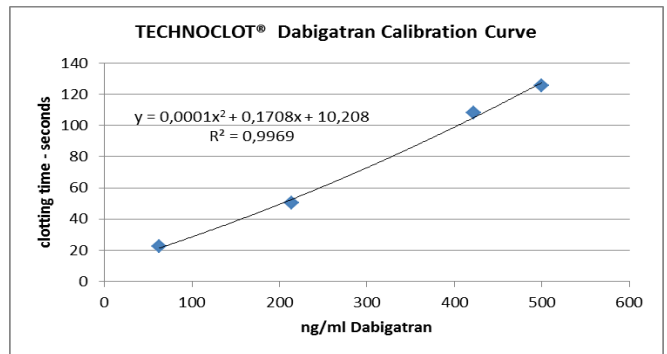
Setting up a reference curve:

X axis: Concentration ng/mL (Dabigatran)

Y axis: Seconds

Draw the best-fit calibration line with linear axis

Example (using Ceveron® alpha):



Measuring concentration of samples

All samples diluted 1:8 can be read off directly from the appropriate reference curve. For other dilutions the value read off from the calibration curve has to be multiplied by the additional dilution factor. It is recommended to run controls with every test in order to ensure accuracy and reproducibility of the results.

REFERENCE RANGE

Pradaxa does not in general require routine anticoagulant monitoring. Please refer to the local product information or Summary of Product Characteristics (SmPC) for Pradaxa for more information.

ASSAY RANGE

The assay range for Dabigatran is 40 – 500 ng/ml. The limit of detection (LoD) for Dabigatran is 50 ng/ml.

PERFORMANCE CHARACTERISTICS

Performance data are given below. Results obtained in individual laboratories may differ.

PRECISION

Reproducibility was determined with different samples (in series and day to day). The following results were obtained:

Sample	Intra assay		Inter assay	
	Sample 1	Sample 2	Sample 1	Sample 2
n	21	21	16	16
Mean ng/mL	114	326	132	347
CV (%)	6.7	4.2	7.7	7.1

COMPARISON OF METHODS OR CORRELATION

Following correlation was obtained in comparing TECHNOCLOT® DTI (Technoclone) with HEMOCLOT® TI (Hyphen) Dabigatran method: Dabigatran samples: n=27 R² = 0.986

INTERFERENCES

Heparin: no interference up to 1.2 IU/mL UFH or LMW

LITERATURE

Please contact Technoclone or your local distributor.