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TECHNOCHROM® Protein C
For research use only

GB

REF 5341013 TECHNOCHROM® Protein C Σ 30

Symbols key / Symbolschlüssel / interpretazione dei simboli / explicación de símbolos / explicação dos símbolos / clé des symboles / Symbolnyckel / symbolforklaring / Tegnforklaring / Κλειδί συμβόλων / Използвани символи / символы / Klíčova slova / Značenje simbola			
	Manufacturer		Expiry date
	Storage temperature		Consult instructions for use
AQUA	Distilled water	Σ	Determinations
BUF	Reaction buffer	LOT	Lot
CAL	Calibrator	MTP	Microtiter plate
CONJ	Conjugate	REF	Catalogue number
CONT	Control	RTU	Ready to use
DIL	Dilute or dissolve in	STOP	Stop solution
INC	Incubation buffer	SUB	Substrate
RUO	For resarch use only	WASH	Washing solution concentrate

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TECHNOCHROM® Protein C

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PRODUCT DESCRIPTION

INTENDEND USE

For 30 photometric Protein C (PC) determinations (test volume 0.85 mL and 1.15 mL).

TEST PRINCIPLE

$$\text{Protein C} \xrightarrow{\text{(Protac)}} \text{Protein Ca}$$

$$\text{Pad-Pro-Arg-pNA} \cdot \text{AcOH} \xrightarrow{\text{(Protein Ca)}} \text{Pad-Pro-Arg-OH} \cdot \text{AcOH} + \text{p-nitroaniline}$$

COMPOSITION

Reagent kit for 30 photometric Protein C determinations.

mL	reagent	other data
3 x 1	Substrate PCa-2	6 µmoL, Pad-Pro-Arg-pNA.AcOH
3 x 1	Protac®	Extract of the venom of Agkistrodin contortix
1 x 1	Ref. Standard PC 1	~ 125% PC (~ 1.25 IU/mL)
1 x 1	Ref. Standard PC 2	~ 75% PC (~ 0.75 IU/mL)
1 x 1	Ref. Standard PC 3	~ 25% PC (~ 0.25 IU/mL)
1 x 60	Protein C buffer	Tris (6.1 g/L)-NaCl (12.7 g/L)-Albumin (0.1%)-buffer, pH 8.4

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes
- Distilled water
- For the endpoint method: 20 % acetic acid.
- Control Plasma Normal and Abnormal

REF	5020040	Coagulation Control N	5 x 1 mL
REF	5020020	Coagulation Control N f. Ceveron	5 x 1 mL
REF	5020050	Coagulation Control N	50 x 1 mL
REF	5020025	Coagulation Control N f. Ceveron	50 x 1 mL
REF	5021055	Coagulation Control A	5 x 1 mL
REF	5021035	Coagulation Control A f. Ceveron	5 x 1 mL
REF	5021060	Coagulation Control A	50 x 1 mL
REF	5021040	Coagulation Control A f. Ceveron	50 x 1 mL

WARNING AND PRECAUTIONS

- For 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 Ref. Standards 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:

Reagent	+37°C	RT (+20 ... 25°C)	+4°C	-20°C
Substrate PCa-2	8 hours	1 week	1 month	6 months
Protac®	-	3 days	1 week	6 months
Ref. Std. PC 1-3	-	8 hours	2 days	6 months

Avoid contamination with micro-organisms.

TEST PROCEDURE

PREPARATION OF PLASMA SAMPLES

Plasma separation:

Mix 9 parts of venous blood and 1 part sodium citrate solution (0.11 mol/L) and centrifuge for 15 minutes at a RCF of at least 2500 (corresponding to DIN 58905). Store the plasma at room temperature (up to 1 day). Stability at –20°C: 6 months.

PREPARATION OF REAGENT

All reagents including distilled water should have reached room temperature before use. The lyophilized reagents are dissolved in the volume of distilled water indicated and are ready for use after 10 minutes. For standardization test a reconstitution time of 30 min is recommended.

PERFORMANCE OF THE TEST

CEVERON

Technoclone provides Application sheets for Ceveron®. The Application sheets contain analyser/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 sheets supersedes the information in this instruction for use. Please consult the instruction manual of the Ceveron®.

MANUAL

Preheat the plasma sample and Protac® to room temperature and the Substrate PCa to +37°C.
Wave length: 405 nm
Light path: 1 cm
Pipette into a plastic tube or cuvette. Measurement against air.

A) Endpoint method

Dilute the Substrate PCa-2 1:5 with PC-buffer (1 part substrate + 4 parts buffer).

For the blank value, strictly follow the order of pipetting given.

Sample			Blank		
Final volume	0.85 mL	1.15 mL	Final volume	0.85 mL	1.15 mL
Sample	0.05 mL	0.05 mL	Acetic acid 20 %	0.20 mL	0.50 mL
+ Protac®	0.10 mL	0.10 mL			
Mix and incubate for exactly	5 min +37°C		Mix	-	-
+ Substrate-buffer-mix (1+4) 37 °C	0.50 mL	0.50 mL	+ PC buffer +37°C	0.60 mL	0.60 mL
Mix and incubate for exactly	3 min-+37°C- 5 min		Mix	-	-
+ Acetic acid (20%)	0.20 mL	0.50 mL	+ Sample	0.05 mL	0.05 mL

B) Kinetic Method

Dilute the Substrate PCa-2 1:6 with PC-buffer (1 part substrate + 5 parts buffer).

Sample + Protac*	0.05 mL 0.10 mL
Mix and incubate for exactly + Substrate-buffer-mixture (1 + 5), 37°C	5 min +37°C 0.60 mL
Mix and determine ΔA/min linear course (r = 0.999)	3 min

ANALYSES RESULTS

CALIBRATION CURVE

Each Reference Standard PC is reconstituted with 1 mL distilled water. The reconstituted standard is used undiluted and treated in the same way as the sample.
The absorbance's obtained (A), or ΔA/min respectively are plotted on graph paper against the % of normal indicated on the labels of the Reference Standard, and linearly joined.

In order to establish a reference curve the reference Standard PC is diluted with PC-buffer 1:1, 1:1.33, 1:2 and 1:4 and is tested like a sample.

Example (kinetic and endpoint method):

Ref. Std. PC	End point $A_{sample} - A_{blank}$ 0.85 mL	1.15 mL	Kinetic ΔA/min	IU PC/mL	% of normal
1	0.474	0.565	0.126	1.23	123
2	0.294	0.344	0.072	0.71	71
3	0.109	0.121	0.024	0.22	22

STANDARDIZATION

The Reference Standard is calibrated against the Reference Preparation of the WHO.

REFERENCE RANGE

70 – 130 % of normal

LIMITATION OF THE TEST

Test results are not based in plasmas containing up to 2 I.U. heparin/mL.

LITERATURE

Please contact Technoclone or your local distributor.