Fletcher Trait Plasma

For research use only

GB

REF 5205006 Fletcher Trait Plasma 2 x 1 mL

Symbols key			
	Manufacturer		Expiry date
	Storage temperature		Consult instructions for use
RUO	For resarch use only		Determinations
AQUA	Distilled water	LOT	Lot
BUF	Reaction buffer / Reaktionspuffer	MTP	Microtiter plate
CAL	Calibrator	REF	Catalogue number
CONJ	Conjugate	RTU	Ready to use
CONT	Control	STOP	Stop solution
DIL	Dilute or dissolve	SUB	Substrate
INC	Incubation buffer	WASH	Washing solution concentrate

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PRODUCT DESCRIPTION

INTENDEND USE

Fletcher Trait Plasma is used for diagnosing pre-kallikrein deficiency. A deficiency in pre-kallikrein will prolong the activated partial thromboplastin time (aPTT) considerably but does not usually result in the expected haemorrhagic tendency. This abnormality in the activating phase of the aPTT can be corrected in vitro by adding Factor XII Deficient Plasma or Fitzgerald Trait Plasma (HMW-Kininogen Deficient Plasma). In addition, a prekallikrein deficiency will also affect fibrinolysis, kinin formation and the complement system.

COMPOSITION

Fletcher Trait Plasma is a lyophilized and stabilized human pre-kallikrein deficiency plasma.

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes - Distilled water - Solutions/buffers:

REF	5279025	$CaCl_2$ 50 mmol/L Solution	100 mL
REF	5400045	Citrate-Sodiumchloride-Buffer	60 mL

- Reagents

REF	5035060	Dapttin® TC	5 x 2 mL
REF	5035090	Dapttin® TC	6 x 10 mL

- Control and Calibration Plasma

REF	5020040	Coagulation Control N	5 x 1 mL
REF	5021055	Coagulation Control A	5 x 1 mL
REF	5220110	Coagulation Reference	5 x 1 mL

WARNING AND PRECAUTIONS

- RUO 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.
- This lot of reagents prepared from human blood and each single plasma used for this lot are HB_sAg, HIV 1/2 Ab and HCV Ab negative (see package label and vial label).

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*	RT* Ceveron® alpha	-20 °C
2 hours	2 hours	1 month

Upon storage, caps should be screwed tightly.
*=room temperature: +18…25 °C

TEST PROCEDURE

PREPARATION OF PLASMA SAMPLES

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.
Before carrying out the test, the specimens plasma is diluted 1:100 using the Citrate-Sodium chloride-Buffer; dilution is to be carried out in two stages on a 1:10 scale (for instance 0.05 mL and 0.45 mL each). For very low and very high pre-kallikrein levels, however, other dilutions should be used.

PREPARATION OF REAGENT

The lyophilized reagent is reconstituted with 1 mL of distilled water and allowed to stand for 10 min at room temperature[1]. Prewarm the $CaCl_2$ solution to +37 °C.

SUGGESTED PERFORMANCE OF THE TEST

The results obtained with the test arrangement as suggested depend to a large extent on the respective lot of the PTT reagent used. Should the values not seem plausible, the pre-dilution of the plasma sample and/or the incubation period should be varied accordingly.

CEVERON

Technoclone provides application sheets for Ceveron® alpha. 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® alpha.

MANUAL Pipetting scheme:

0.10 mL	Fletcher Trait Plasma
+ 0.10 mL	diluted plasma sample
+ 0.10 mL	PTT reagent (f.i. Dapttin TC) (shake briefly and incubate for 1 min. at +37 °C)
+ 0.10 mL	$CaCl_2$ 50 mmol/L solution + 37 °C
	determine the point of coagulation

ANALYSES RESULTS

REFERENCE RANGE

70-120 % of normal

CALCULATION OF THE RESULTS

The predilution 1:100 of the plasma samples is not to be considered in the evaluation. The plasma samples prediluted at a ratio of 1:100 may be read off directly from the calibration curve. If dilution ratios other than 1:100 are used, the % pre-kallikrein values of the calibration curve may be converted by using the following formula:

$$\frac{\text{\% pre-kallikrein}}{100} \times \text{dilution} = \text{\% pre-kallikrein of the sample}$$

CALIBRATION CURVE

The Coagulation Reference is a lyophilised normal plasma pool to be dissolved in 1 mL distilled water or accordance with data indicated on the table. With Citrate-Sodium chloride-Buffer predilution is effected in line with the following instructions: 1:100 (twice one part Coagulation Reference plus 9 parts Citrate-Sodium chloride-Buffer). Prepare a geometric series of dilutions (1:1 to 1:32) of the predilution (1:100). The 1:1 ratio corresponds to the predilution 1:100.

Predilution	Dilution of calibration curve					
1:100	1:1	1:2	1:4	1:8	1:16	1:32
% pre-kallikrein	100	50	25	12.5	6.3	3.1

Determine the coagulation time of the different dilutions and plot on log-log paper (x-axis: log activity in %; y-axis: log coagulation time in sec).

QUALITY CONTROL

In order to verify the accuracy of the results, Coagulation Control A and N should always be tested in the same way as the specimen's plasma.

LIMITATION OF THE TEST

- Incorrect sample handling can lead to partial activation of the coagulation factors and to falsely elevated single factor determinations.
- A new calibration is required for each batch of reagents where a calibration curve is necessary and for each instrument used. Also, a new calibration is recommended, if software changes are introduced or following a major service of either instruments or equipment.

APPLICATIONS FOR INSTRUMENTS

Application sheets are available from Technoclone or your local distributor upon request.

LITERATURE

Please contact Technoclone or your local distributor.

[1] For standardisation a reconstitution time of 30 min is recommended.