Fitzgerald Trait Plasma

For research use only

GB

REF 5204006 Fitzgerald Trait Plasma 2 x 1 mL

Symbols key			
	Manufacturer		Expiry date
	Storage temperature		Consult instructions for use
AQUA	Distilled water		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 research use only	WASH	Washing solution concentrate

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PRODUCT DESCRIPTION

INTENDEND USE

Fitzgerald Trait Plasma is used in the investigation of high molecular weight kininogen deficiency. HMW-kininogen deficient plasma show a prolonged coagulation time in the aPTT test. This abnormality is not accompanied by the expected haemorrhagic tendency. The aPTT abnormality can be neutralised in vitro by the addition of factor XII deficient plasma or Fletcher Trait Plasma (prekallikrein deficient plasma). In addition on the effect on the aPTT test, Fitzgerald Trait Plasma also shows abnormalities in fibrinolytic activity, the formation of kinins and the permeability of the vascular wall.

COMPOSITION

Fitzgerald Trait Plasma is a immune-adsorbed lyophilized and stabilized human high molecular weight kininogen deficient 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

*** or any other package sizes, special Ceveron® alpha or Technoclot Control and Calibration reagents of Technoclone.

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.
- 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®)	-20 °C
2 hours	2 hours	1 month

Upon storage, caps should be screwed tightly. *=room temperature

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 (corresponding to DIN 58905). Store the plasma at room temperature.
Before carrying out the test, the sample plasma is diluted 1:10 (0.05 mL + 0.45 mL) using the Citrate–Sodiumchloride-Buffer. For very low and very high HMW Kininogen 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.

PERFORMANCE OF THE TEST

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	Fitzgerald Trait Plasma
+ 0.10 mL	diluted plasma sample
+ 0.10 mL	PTT reagent (f.i. Dapttin TC) (shake briefly and incubate for 4 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 1:10 of the plasma samples is not to be considered in the evaluation. The plasma samples prediluted at a ratio of 1:10 may be read off directly from the calibration curve. If dilution ratios other than 1:10 are used, the % HMW kininogen values of the calibration curve may be converted by using the following formula:

$$\frac{\text{\% HMW-kininogen-content}}{10} \times \text{dilution} = \text{\% HMW kininogen of the sample}$$

CALIBRATION CURVE

The Coagulation Reference is a lyophilised normal plasma pool to be dissolved in 1 ml distilled water or in accordance with data indicated on the table. With Citrate-Sodiumchloride-Buffer predilution is effected in line with the following instructions: 1:10 (one part Coagulation Reference plus 9 parts Citrate-Sodiumchloride-Buffer). Prepare a geometric series of dilutions (1:1 to 1:32) of the predilution (1:10). The 1:1 ratio corresponds to the predilution 1:10.

Predilution	Dilution of calibration curve					
1:10	1:1	1:2	1:4	1:8	1:16	1:32
% HMW kininogen	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 sample 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.