Factor II, VII, and X Deficient Plasma

For research use only

GB

REF	5114008	Factor II Deficient Plasma, immunads.	5 x 1 mL
REF	5144015	Factor VII Deficient Plasma, immunads.	5 x 1 mL
REF	5174006	Factor X Deficient Plasma, immunads.	5 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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Factor II-, VII- and X Deficient Plasma

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PRODUCT DESCRIPTION

INTENDEND USE

FII-, FVII-, and FX Deficient Plasmas are used for the determination of the coagulation factors II, VII and X with the one-stage method using thromboplastin reagent.

COMPOSITION

FII-, FVII-, and FX Deficient Plasmas are lyophilised stable human deficient plasmas with coagulation activities < 1 % of the corresponding factors. FII, FVII and X Deficient Plasmas were obtained by immunadsorption.

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes: 50 µL, 100 µL, 900 µL, 1000 µL
- Solutions: Distilled water

REF	5400045	Citrate-Sodiumchloride-Buffer	60 mL

- Reagents ***

REF	5003009	Technoplastin HIS	12 x 2 mL
REF	5003220	Technoclot PT PLUS	5 x 4 mL
REF	5003222	Technoclot PT PLUS	10 x 10 mL

- Control Plasmas and Calibrators ***

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*	15-18 °C	-20 °C
2 hours	8 hours	1 month

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

When storing, the tubes must be securely capped.
Deep frozen reagent must be thawed for at least 10 minutes at 37°C and mixed thoroughly before use.
Repeated freezing is not recommended

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). The plasma sample can be stored at room temperature for 4 hours. **Do not keep the plasma at 2-8°C** because factor VII can be activated by the kallikrein system in this temperature range. Before performance the test, dilute the plasma sample 1:10 with Citrate-Sodiumchloride-buffer (0.1 ml + 0.9 ml).

PREPARATION OF REAGENT

Reconstitute the lyophilised reagents in the prescribed quantities of distilled water and allow them to stand for 10 min at room temperature[1].

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

Prewarm the thromboplastin reagent (Technoplastin HIS, TC-Plastin or Technoclot PT) to 37 °C.
Pipetting scheme:

0.05 mL	Factor II-, VII- or X Deficient Plasma
+ 0.05 mL	diluted sample (shake briefly and incubate for 1 minute at 37 °C)
+ 0.20 mL	thromboplastin reagent (Technoplastin HIS, TC-Plastin or Technoclot PT) (start the stop watch)
	mix and determine the point of coagulation

Any other sensitive Ca-thromboplastin without factor additives can be used.

ANALYSES RESULTS

REFERENCE RANGE

70-120 % of normal

CALCULATION OF THE RESULTS

Values for 1:10 diluted plasma samples can be read off directly from the calibration curve.
When other dilutions are used, the activities in % of the calibration curve can be calculated by the following formula:

$$\frac{\text{\% coagulation activity}}{10} \times \text{chosen dilution} = \text{\% coagulation activity of the corresponding factor}$$

CALIBRATION CURVE

For the corresponding factor determination reconstitute the Coagulation Reference with the volume given in the table (allow to stand for 30 minutes)
A predilution of 1:5 is attained by using a citrate NaCl buffer in the ratio 1:5 (1 part Coagulation Reference plus 4 parts citrate NaCl buffer). Prepare a geometric series of dilutions (1:1 to 1:64) of the predilution (1:5). The indication 1:1 corresponds to the predilution 1:5.
Example:

Predilution	Dilution of calibration curve						
1:5	1:1	1:2	1:4	1:8	1:16	1:32	1:64
% FII, VII, X	200	100	50	25	12.5	6.3	3.1

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

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 (especially F V and F VIII) and to falsely elevated single factor determinations.
Lupus anticoagulant can affect the apparent factor activity in single factor determination.
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 recommendend