Factor V Deficient Plasma immunads.

For research use only

GB

REF 5134004 Factor V 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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F V Deficient Plasma, immune-adsorbed

GB

PRODUCT DESCRIPTION

INTENDEND USE

Factor V deficient plasma immunads. is used to determine the clotting factor V with the one stage method, also using a thromboplastin suitable for Factor V determination. The F V immune-adsorbed deficiency plasma may be used for prediluting sample specimens in determining APC resistance. The cut-off for differentiating the F V Leiden mutation has to be specifically established for the deficiency plasma – using the respective reagent and automatic equipment.

COMPOSITION

The Factor V deficient plasma immunads. is an immune-adsorbed lyophilised human deficient plasma with a clotting activity <3 %. F V Deficient Plasma immune-adsorbed is prepared from normal human plasma.

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes - Distilled water - Solutions/buffers:

REF	5400045	Citrate-Sodium-Chloride Buffer	60 mL

- Reagents ***

REF	5003128	TECHNOCLOT® PT	10 x 4 mL
REF	5003220	TECHNOCLOT® PT Plus	5 x 4 mL

- Calibrators and Control Plasmas ***

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

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* (Ceveron **)	-20 °C
2 hours	1 month

Repeated freezing is not recommended.

*= room temperature
** = in the Ceveron® alpha in the respective control area in the sample tray.

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 (up to 1 day). Before carrying out the test, the sample plasma is diluted 1:10 (0.1 mL + 0.9 mL) using the Citrate-Sodium-Chloride buffer. If the presence of inhibitors is suspected, various dilutions of the plasma sample should be tested.

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 sheet supersedes the information in this instruction for use. Please consult the instruction manual of the Ceveron® alpha.

MANUAL

Pipetting scheme:

0.05 mL + 0.05 mL	Factor V Deficient Plasma, immune-adsorbed diluted plasma samples (shake briefly and incubate for 1 min. at 37 °C)
+ 0.20 mL	thromboplastin reagent
	Mix and determine the point of coagulation

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:

$$\frac{\text{\% FV content}}{10} \times \text{dilution} = \text{\% FV of the sample}$$

CALIBRATION CURVE

Reconstitute the Coagulation Reference. A predilution of 1:5 is attained by using an Citrate-Sodium-Chloride buffer in the ratio 1:5 (1 part Coagulation Reference plus 4 parts buffer). Prepare a geometric series of dilutions (1:1 to 1:64) of the predilution (1:5). The 1:1 ratio corresponds to the predilution 1:5.

Predilution	Dilutions of calibration curve						
1:5	1:1	1:2	1:4	1:8	1:16	1:32	1:64
% FV	200	100	50	25	12.5	6.3	3.1

Determine the coagulation times of the geometric series of dilutions and plot them on semilog paper (x-axis: log activity %; y-axis: 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 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 see our webpage www.technoclone.com or contact your local distributor.

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