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Factor IX Deficient Plasma immunads.
For research use only

GB

REF	5164003	Factor IX Deficient Plasma, immunads.	5 x 1 mL
REF	5164004	Factor IX Deficient Plasma, immunads.	50 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 resarch use only	WASH	Washing solution concentrate

Technoclone Herstellung von
Diagnostika und Arzneimitteln GmbH
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Factor IX Deficient Plasma, immunads.

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PRODUCT DESCRIPTION

INTENDEND USE

Factor IX deficient plasma immunads. is used in the determination of Coagulation Factor IX by one-stage method based on the Activated Partial Thromboplastin Time (aPTT).

COMPOSITION

The Factor IX deficient plasma immunads. is an immune-adsorbed lyophilised, stabilised human plasma with a Factor IX content of <1%, prepared from HIV 1/2 Ab negative plasmas.

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes - Distilled water - Solutions/buffers:

REF	5410010	Imidazole buffer	50 mL
REF	5277015	$CaCl_2$ 25 mmol/L solution	100 mL

- Reagents**

REF	5035060	Dapttin® TC	5 x 2 mL
REF	5035105	Siron LS (aPTT liquid)	2 x 4 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 of Technoclone.

*** 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* (Ceveron****)	-20 °C
3 hours	1 month

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

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

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).
Store the plasma at room temperature (up to 4 hours). If quickly frozen, samples can be stored at -20°C up to 15 days or at -80°C up to 1 month. Thaw the sample at 37°C.
Before carrying out the test, the sample plasma is diluted 1:5 (0.1 mL+ 0.4 mL) using the imidazole buffer. For very low and very high Factor VIII levels, however, other dilutions should be used. If the presence of inhibitors is suspected, various dilutions of the plasma sample should be tested.

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] Prewarm the $CaCl_2$ 25 mmol/L 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 these instruction for use. In this case the information contained in the application sheets supersedes the information in these instruction for use. Please consult the instruction manual of the Ceveron® alpha.

MANUAL

Pipetting scheme:

0.1 mL	Factor IX Deficient Plasma, immune-adsorbed
+ 0.1 mL	diluted plasma samples
+ 0.1 mL	PTT reagent
	(shake briefly and incubate for 3 min. at 37 °C)
+ 0.1 mL	$CaCl_2$ 25 mmol/L solution 37°C
	determine the point of coagulation

ANALYSES RESULTS

REFERENCE RANGE

70-120 % of normal

CALCULATION OF THE RESULTS

The predilution 1:5 of the plasma samples is not to be considered in the evaluation.
The plasma samples prediluted at a ratio of 1:5 may be read off directly from the calibration curve. If dilution ratios other than 1:5 are used, the % F IX values of the calibration curve may be converted by using the following formula:

$$\frac{\text{\% FIX content}}{5} \times \text{dilution} = \text{\% FIX of the sample}$$

CALIBRATION CURVE

Reconstitute the Coagulation Reference as indicated in the table. A predilution of 1:5 is attained by using an imidazole buffer in the ratio 1:5 (1 part Coagulation Reference plus 4 parts buffer). Prepare a geometric series of dilutions (1:1 to 1:128) of the predilution (1:5). The 1:1 ratio corresponds to the predilution 1:5.

Predilution	Dilutions of calibration curve							
1:5	1	1:2	1:4	1:8	1:16	1:32	1:64	1:128
% FIX	100	50	25	12.5	6.3	3.13	1.56	0.78

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, abnormal control plasma (i.e. Coagulation Control A) and normal control plasma (i.e. Coagulation Control 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

PERFORMANCE CHARACTERISTICS

Performance data are given below. Results obtained in individual laboratories may differ.

PRECISION

Reproducibility was determined with different samples (in series and day to day).
The following results were obtained:

	Intra assay		Inter assay	
Sample	Sample 1	Sample 2	Sample 1	Sample 2
n	96	74	6	6
MW (sec)	40.2	49.1	38.7	61.4
SD (%)	0.637	1.233	1.429	2.708
CV (%)	1.6%	2.5%	3.69%	4.41%

COMPARISON OF METHODS OR CORRELATION

When WHO Plasma and SSC Plasma FVIII were tested for FIX with the FIX deficient plasma method the obtained correlation (%) was:

FIX immundepl. method: n=50 $y = 0,994x + 2,1573$ $R^2 = 0,9891$

LINEARITY

FIX method: 0,8 – 100 (Activity %)

DETECTION LIMIT

FIX method: 0,8% (Activity %)

LITERATURE

Please contact Technoclone or your local distributor.

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