Thrombin Reagent

For research use only

GB

REF 5100005 Thrombin Reagent 6 x 6 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

Technoclone Herstellung von
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PRODUCT DESCRIPTION

INTENDEND USE

Thrombin Reagent is used for the determination of the Thrombin Time (TT) in order to check:

- the fibrinogen level (fibrin degradation products)
- heparin therapy
- fibrinolytic therapy

COMPOSITION

The standardised Thrombin Reagent contains bovine thrombin.

MATERIAL REQUIRED (not supplied with the kit)

- Pipette: 200 µL - Distilled water
- Control plasma normal and abnormal**

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

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*	12°C (Ceveron)	-20 °C
8 hours	24 hours	1 month

The vials can be only frozen once.
Upon storage, caps should be screwed tightly. *=room temperature

TEST PROCEDURE

PREPARATION OF PLASMA SAMPLES

Plasma separation:
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.

PREPARATION OF REAGENT

Carefully open the vial and reconstitute the lyophilised reagent in 6 mL (2 mL in case of samples containing heparin) distilled water by slowly rotating the vial. Allow the reconstituted reagent to stand for 10 minutes at room temperature. For standardisation a reconstitution time of 30 min is recommended.

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:

0.20 mL citrated plasma (room temperature)
Incubate for 1 minute at 37°C[1]
+ 0.20 mL Thrombin Reagent (room temperature)
determine the point of coagulation

[1] When using plastic tubes, incubate for 2 minutes at 37°C.

LIMITATION OF THE TEST

The values found when testing normal control plasma (i.e. Coagulation Control N) and abnormal control plasma (i.e. Coagulation Control A) should be compared to the value given on the data-key for the corresponding lot of Control plasma.
If the results obtained are outside the recommended range, avoid measuring samples until the problem is solved.
If coagulation analyzers with other measurement principles are used, the obtained coagulation times can deviate from the stated confidence range. In this case it is recommended that each laboratory establishes its own reference range.

ANALYSES RESULTS

CALCULATION OF THE RESULTS

The results of the thrombin time are assayed in seconds.
See "REFERENCE RANGE"

- In order to control the normal value, normal control plasma (i.e. Coagulation Control N) should be included in each batch of assays.
- For quality control in the abnormal range, the use of abnormal control plasma (i.e. Coagulation Control A) or a control plasma containing heparin is advisable.

REFERENCE RANGE

NORMAL AND THERAPEUTIC RANGES

	3.3 IU Thrombin/mL (reconstituted in 6 mL distilled water)	10 IU Thrombin/mL (reconstituted in 2 mL distilled water)
Normal range	< 22 sec.	6 – 11 sec.
Heparin therapy*	45 – 120 sec.	20 – 60 sec.
Fibrinolytic therapy (urokinase*)	> 120 sec.	20 – 60 sec.

STANDARDIZATION

No international calibrator is available for the standardization of thrombin time. An in-house reference batch is established in order to avoid batch-to batch variation.

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	11	12	11	11
MV sec	11.7	15.1	12.1	14.9
SD (%)	0.234	0.273	0.519	0.379
CV (%)	2.0	1.81	4.29	2.55

COMPARISON OF METHODS OR CORRELATION

Following coorelation (%) was obtained in comparing THROMBIN REAGENT (Technoclone) with THROMBIN REAGENT (Roche) in THROMBIN TIME methode:

Thrombin time method: n=94 $y = 1.0083x + 3.2242$ $R^2 = 0.8123$

DETECTION LIMIT

Heparin: LMW: $\leq$ 1E/ml (3,3IU/ml), $\leq$ 2E/ml (10IU/ml)
Triglyceride: no detection limit to 500mg/dl
Bilirubin: no detection limit to 0.4mg/dl

LITERATURE

* R. Zimmermann et al.: Laboratory Control of Heparin and Thombolytic Therapy by Thrombin Clotting Time and Activated Partial Thromboplastin Time. Ärztl. Lab. 33: 121-126 (1987)