TECHNOPLASTIN® HIS

For research use only

GB

REF	5003009	TECHNOPLASTIN® HIS	12 x 2 mL
REF	5003010	TECHNOPLASTIN® HIS f. Ceveron	12 x 4 mL
REF	5003030	TECHNOPLASTIN® HIS	2 x 10 mL
REF	5003026	TECHNOPLASTIN® HIS	6 x 10 mL
REF	5003028	TECHNOPLASTIN® HIS f. Ceveron	6 x 20 mL
REF	5003021	TECHNOPLASTIN® HIS	20 x 10 mL
REF	5003022	TECHNOPLASTIN® HIS f. Ceveron	20 x 20 mL

Symbols key

	Manufacturer		Expiry date
	Storage temperature		Consult instructions for use
AQUA	Distilled water	Σ	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
Diagnostika und Arzneimitteln GmbH
Brunner Str. 67 - 1230 Vienna, Austria

TECHNOPLASTIN® HIS

GB

Ca-thromboplastin for the determination of the prothrombin time (PT, Quick)

PRODUCT DESCRIPTION

INTENDEND USE

TECHNOPLASTIN® HIS is used for the determination of the prothrombin time (Quick test). This screening test is used

- for the control of blood coagulation disorders of the extrinsic system,
- for the surveillance of oral anticoagulant therapy,
- for separate determination of individual coagulation factors of the extrinsic system,
- to check the liver's function of synthesizing coagulation factors in hepatopathies.

A heparin neutralizing agent in the reagent permits the assessment of plasma obtained from samples on conventional heparin therapy (0.2 - 0.8 U. hep./mL).

COMPOSITION

TECHNOPLASTIN® HIS (HIS = **H**eparin**I**n**S**ensitive) is a standardised Ca-thromboplastin reagent obtained from rabbit brain which is characterized by sensitivity to coagulation factors II, V, VII and X. In addition, the reagent contains a heparin neutralizing agent.

MATERIAL REQUIRED (not supplied with the kit)

- Pipettes
- Distilled water
- Control Plasmas and Calibrators

REF	5020040	Coagulation Control N **	5 x 1 mL
REF	5011050	Coagulation Control AK **	5 x 1 mL
REF	5010004	AK-Calibrant	4 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:

37 °C	RT*	12°C (Ceveron)	+2…8 °C	-20 °C
6 hours	24 hours	5 days	6 days	2 months

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 an RCF of at least 2500 (corresponding to DIN 58905). Keep the plasma at room temperature (up to 4 hours).

PREPARATION OF REAGENT

The lyophilized reagent is to be reconstituted with the indicated volume of distilled water at room temperature and may be used immediately. For Standardisation a reconstitution time of 30 min is recommendend.

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 this instruction for use. Please consult the instruction manual of the Ceveron® alpha.

MANUAL

Pipette the following substances into a test tube preheated to 37°C:

	Citrated plasma	0.1 mL
	Incubate for 1 min at + 37°C	
+	TECHNOPLASTIN® HIS (37°C)	0.2 mL

Upon addition of TECHNOPLASTIN® HIS, start the stopwatch or the coagulometer resp. and determine the clotting time.

ANALYSES RESULTS

CALCULATION OF THE RESULTS

The prothrombin time is indicated in seconds, in % of normal (Quick), or in INR. Values can be converted by means of the enclosed reference curve in form of a table, considering the indicated method. Reference curves have to be checked for accuracy by means of control plasma prior to use. If the values are beyond the confidence range given for control plasma, a separate reference curve has to be prepared.
For the preparation of the reference curve Technoclone's calibration plasma or the following dilutions of a normal plasma pool (Coagulation Control N) with isotonic saline solution may be used.

% of normal	100 %	50 %	25 %	12.5 %	10 %
dilution	undil.	1+1	1+3	1+7	1+9

These dilutions are to be determined like samples. The mean values of triple determinations are plotted an a reciprocal curve sheet and joined linearly.

The values indicated in % of normal can be transformed to INR according to the enclosed reference curve table. The indication of the prothrombin time in INR, as recommended by the WHO, is based on the following formula:

$$INR = \left(\frac{\text{PT patient plasma (sec)}}{\text{PT normal plasma (sec)}} \right)^{ISI}$$

REFERENCE RANGE

Normal time – approximate value: 13 – 17 sec.
Normal range in % of normal. 70 - > 100 %
Therapeutic range of oral anticoagulants: INR of 2.0 – 4.5 of 20 – 42% of normal, resp.

STANDARDISATION

The reference batch is calibrated against the Secondary Int. Reference Preparation for rabbit brain thromboplastin reagent (plain), RBT/79.
The standardisation is performed by use of the "Simplified calibration procedure" (Loeliger er al. Thrombosis Diathes Haemorrh 33-172, 1975 and Loeliger et al. Thrombosis and Haemostasis 40,272, 1978).

LIMITATION OF THE TEST

Inhibitors of the Lupus type anticoagulant can influence prothrombin time and lead to INRs that do not accurately reflect the true level of anticoagulation.

The choice of anticoagulant (i.e. oxalate instead of citrate) and the condition of the specimen (e.g. hemolyzed, lipemic, parenteral feeding, etc.) may affect results. The latter is particularly true of optical instrumentation measurement of the PT.

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	12	12	24	24
MV INR	0,99	3,14	1,00	3,15
SD (%)	0,012	0,037	0,010	0,039
CV (%)	1,24	1,18	0,91	1,24

COMPARISON OF METHODS OR CORRELATION

Following correlation (INR) was obtained in comparing TECHNOPLASTIN HIS with :

Recombiplastin 2G	y = 1.073x	R^2 = 0.9837
Thromborel S	y = 1.0082x	R^2 = 0.9927

LITERATURE

Moll, St and Ortel, Th. L. Monitoring Warfarin Therapy in samples with Lupus Anticoagulants. Ann Int Med 127, 177-185 (1997).