

REF 5005032 TECHNOCLOT® PT Owren manual, 10 x 4 mL

REF 5005037 TECHNOCLOT® PT Owren manual, 10 x 10 mL

For research use only

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TECHNOCLOT® PT Owren manual - English

INTENDED USE

TECHNOCLOT® PT Owren manual is a thromboplastin reagent for the quantitative determination of Prothrombin Time (PT) in human citrated plasma, capillary blood and venous blood.

SUMMARY

This reagent is sensitive to abnormal levels of the coagulation factors II, VII and X. It is used for the control of blood coagulation disorders of the extrinsic system as well as the monitoring of oral anticoagulant therapy (i.e. warfarin). TECHNOCLOT® PT Owren manual is especially designed to be used with manual methods (i.e. tilting) and semi-automated coagulometers.

REAGENTS

The reagent is lyophilized and contains rabbit brain thromboplastin and adsorbed bovine plasma. The adsorbed plasma is added as a source of factor V and fibrinogen. TECHNOCLOT® PT Owren manual is a combined thromboplastin which already contains CaCl₂.

Materials required (not supplied with the kit)

- Pipettes
- REF 9801025 Capillaries 25µL 2 x 100 pcs.
- Distilled water
- Control Plasma*
- REF 5020040 Coagulation Control N 5 x 1 mL
- REF 5011050 Coagulation Control AK 5 x 1 mL
- REF 5021055 Coagulation Control A 5 x 1 mL
- REF 5005102 TECHNOCLOT® PT Owren Capillary Control Set
- Calibration Plasma
- REF 5010004 AK-Calibrant 4 x 1 mL
- REF 5220110 Coagulation Reference 5 x 1 mL
- REF 5005100 TECHNOCLOT® PT Owren Capillary Calibration Set

* or any other package sizes or TECHNOCLOT® reagents.

Warning and precautions

- RUO – For research use only.
- TECHNOCLOT® PT Owren manual contains no human material.
- TECHNOCLOT® PT Owren manual has been derived from healthy bovine animals approved for human consumption.
- A Material Safety Data Sheet for this product is available from www.technoclone.com

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	+18...25°C	+2...8°C	≤ -20°C
1 hour	6 hours	24 hours	1 month

Frozen reagent must be thawed for at least 10 minutes at +37°C and mixed thoroughly before use.

TEST PROCEDURE

Preparation of the sample – Capillary blood

Make a skin puncture sufficiently deep to produce a free flow of blood. The first drop should always be used. Capillary blood should be tested immediately.

Preparation of the sample - Plasma

Citrated human plasma: Blood is collected into 3.2% Buffered Citrate anticoagulant tubes at a ratio of 9 volumes blood to 1 volume anticoagulant and gently mixed by inversion. Centrifuge at a minimum of 1500 x g for 15 minutes (CLSI Guideline H21-A5) and remove supernatant plasma. Samples may be stored up to two hours at room temperature (+18...25°C).

Preparation of the sample – Venous blood

Blood is collected into 3.2% Buffered Citrate anticoagulant tubes at a ratio of 9 volumes blood to 1 volume anticoagulant and gently mixed by inversion. Samples may be stored up to three hours at room temperature (+18...25°C).

Preparation of reagent

- The distilled water and reagent have to reach room temperature before mixing.
- Add distilled water to the lyophilized reagent as indicated on the vial.
- Allow the reconstituted reagent to stand for 10 minutes
- Then, swirl the reconstituted reagent to obtain a homogenous suspension

Performance of the test – automated use

Technoclone provides an optimized reagent for automated use:

REF 5005044 TECHNOCLOT® PT Owren automated	10 x 4 mL
REF 5005046 TECHNOCLOT® PT Owren automated	10 x 10 mL

Please contact your local Technoclone distributor for further information.

Performance of the test – manual use

Method	Reagent	Sample
Capillary blood	250µL	25µL
Plasma	250µL	15µL
Venous blood	250µL	25µL

- Pipette 250µL of the reagent into small clotting tubes and pre-warm in a water bath at 37°C for at least 3 minutes.
- Dispense the blood sample (for correct volume, see table). Makes sure that the sample is removed from the pipette tip. Start the stop-watch simultaneously.
- Mix blood and reagent by tapping the tube once or twice and leave the tube in the water bath for about 10 seconds.
- The coagulation time is measured from the addition of the sample until clot formation.
- At short intervals tilt gently to observe and record the moment of coagulation.
- For the capillary blood method, the coagulation activity is read from the column for capillary blood in the correlation table.
- For the venous blood- and plasma methods, the coagulation activity is read from the column for plasma or venous blood in the correlation table.

LIMITATION OF THE TEST

- Always use the first drop of capillary blood. Do not use cotton wool before sampling because it initiates coagulation.
- Use only clean pipettes, collecting and clotting tubes.
- Use reconstitution liquid (distilled water) at room temperature. Low temperature might cause flocculation of cold insoluble fibrinogen in the bovine plasma component of the reagent.
- Control that the number on the correlation table corresponds to the batch number of the vial.
- Reference curves have to be checked for accuracy by means of control plasma prior to use. If the values are outside the confidence range given for control plasma, a separate reference curve has to be prepared.

INTERPRETATION OF RESULTS

Each package of TECHNOCLOT® PT Owren manual contains a correlation table for reading the coagulation activity. Be sure that the table corresponds to the actual batch and method. The prothrombin time is indicated in seconds, in % of normal, or in INR. Values can be converted using a reference curve which has to be checked for accuracy by means of control

plasmas prior to use. For the preparation of the reference curve for the plasma and venous blood method AK-Calibrant or the following dilutions of Coagulation Reference with buffer may be used.

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

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

For the preparation of the reference curve for the capillary method TECHNOCLOT® PT Owren Capillary Calibration Set may be used.

The indication of the prothrombin time in INR, as recommended by the WHO, is based on the following formula:

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

The ISI of a thromboplastin is assigned by the manufacturer, and is batch specific. As the ISI value is also influenced by the type of instrument used, an instrument specific ISI is recommended.

NORMAL AND THERAPEUTIC RANGE

Normal time: approximate value: 15 – 20 sec.

Normal: 70%-130% (Lower values may occur in healthy subjects)

Therapeutic range: For oral anticoagulant treatment indications (e.g. warfarin) and duration of treatment, please make reference to local guidelines.

STANDARDISATION

Each batch is standardized against a special batch of TECHNOCLOT® PT Owren manual, a house-standard. This batch is standardized against WHO Int. Reference Preparation for rabbit brain thromboplastin reagent (plain), RBT/05.

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:

Sample	Intra assay		Inter assay	
	1	2	1	2
n	12	17	20	20
MV INR	0.99	3.28	0.98	3.10
SD (%)	0.03	0.07	0.02	0.12
CV (%)	3.5	2.1	2.1	4.0

Comparison of Methods

Following correlation (INR) was obtained in comparing TECHNOCLOT® PT Owren manual with: Normotest® capillary method $y = 1.009x + 0.3168$ $R^2 = 0.8100$

LITERATURE

Please contact Technoclone or your local distributor.

SYMBOL KEYS



Manufacturer

RUO

For research use only



Storage temperature

LOT

Lot



Expiry date

REF

Catalogue number



Consult instructions for use

GTIN

Global Trade Item Number



Biological risk

