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|--------------------------------|----------------------------|-----|
| REF 5005032                    | Technoclot PT Owren manual | ENG |
| REF 5005037                    | Technoclot PT Owren manual |     |
| 3015283RUO Rev. 007 2021/10/21 |                            | RUO |

## Technoclot PT Owren manual - English

### INTENDED USE

Technoclot PT Owren manual is a thromboplastin reagent for the 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 REF 5005032 Technoclot PT Owren manual contains:

|           | Reagent             | Description                                                                                                           |
|-----------|---------------------|-----------------------------------------------------------------------------------------------------------------------|
| 10 x 4 mL | Technoclot PT Owren | Rabbit brain thromboplastin, adsorbed bovine plasma (Factor V and Fibrinogen source), CaCl <sub>2</sub> , lyophilized |

The REF 5005037 Technoclot PT Owren manual contains:

|            | Reagent             | Description                                                                                                           |
|------------|---------------------|-----------------------------------------------------------------------------------------------------------------------|
| 10 x 10 mL | Technoclot PT Owren | Rabbit brain thromboplastin, adsorbed bovine plasma (Factor V and Fibrinogen source), CaCl <sub>2</sub> , lyophilized |

### Material required (not supplied with the kit)

- Precision Pipettes
- Distilled water
- Laboratory timer
- REF 9801025 Capillaries 25µL
- REF 5020040 Coagulation CON N or
- REF 5020050 Coagulation CON N
- REF 5011050 Coagulation CON AK or
- REF 5011060 Coagulation CON AK
- REF 5021055 Coagulation CON A or
- REF 5021060 Coagulation CON A
- REF 5005102 Technoclot PT Owren Capillary CON
- REF 5010004 AK-Calibrant or
- REF 5220110 Coagulation Reference or
- REF 5220120 Coagulation Reference or
- REF 5005100 Technoclot PT Owren Capillary CAL

### 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.
- This reagent is intended for use by personnel trained in laboratory procedures and universal precautions for the use of chemicals and potentially biohazardous substances must be applied.
- All human blood or plasma products as well as samples must be considered as potentially infectious. They have to be handled with appropriate care and in strict observance of safety regulations. The rules pertaining to disposal are the same as applied to disposing hospital waste.
- Calibrators and control plasmas are made from human blood and any individual plasma involved in the procedure is tested HbsAg, HIV 1/2 Ab and HCV-Ab-negative. However, all human blood products should be handled as potentially infectious material
- Get a Material Safety Data Sheet for this product from www.technoclone.com.

### Stability and storage

The expiry date printed on the labels is only applicable to storage of the unopened containers at 2...8 °C.

Stability opened/ in use:

| 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

Collect nine parts of freshly drawn venous blood in one part trisodium citrate (3.2 %). Refer to CLSI Document H21-A5 for instructions on specimen collection, handling, and storage.

Samples may be stored up to two hours at room temperature (18...25 °C).

#### Preparation of the sample – Venous blood

Collect nine parts of freshly drawn venous blood in one part trisodium citrate (3.2 %) and gently mixed by inversion.

Samples may be stored up to three hours at room temperature (18...25 °C).

#### Preparation of reagent

Before starting the test, all the required components are to be brought to room temperature.

When reconstituting plasmas, mixing reagents or buffers avoid foaming.

Due to high fibrinogen content of the reagent, protein agglomeration can be visual after reconstitution without impacting the assay performance.

- *PT Owren Reagent*: Dissolve one bottle of lyophilized reagent in 4 mL (REF: 5005032) or 10 mL (REF: 5005037) distilled water and swirl gently. Allow the reconstituted material to stand for 10 minutes at room temperature before use. Invert to mix before use.

#### Performance of the test – automated use

Technoclone provides an optimized reagent for automated use:

REF 5005044 Technoclot PT Owren automated or

REF 5005046 Technoclot PT Owren automated

Please contact your local Technoclone distributor for further information.

### Performance of the test – manual use

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

- Pipette 250 µL 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). Make 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 patients 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:

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

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 refer to local guidelines.

### PERFORMANCE CHARACTERISTICS

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

#### Comparison of Methods

Following correlation [INR] was obtained in comparing Technoclot PT Owren manual with Normotest capillary method:  
 $y = 1.009x + 0.3168$        $R^2 = 0.8100$

#### Precision

Reproducibility was determined with different samples

| Sample code      | Assigned value [INR] | CV % within run | CV % total |
|------------------|----------------------|-----------------|------------|
| Normal control   | 0.99                 | 3.5             | 2.1        |
| Abnormal control | 3.28                 | 2.1             | 4.0        |

### 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).

### LITERATURE

Please contact Technoclone www.technoclone.com or your local distributor.

### EDITORIAL NOTE

This document is available in several languages. The translations have been done using the master document in English. In the event of doubts or discrepancies, the wording in the master document in English shall take precedence.



Manufacturer

LOT Lot



Storage temperature

RUO Research Use Only



Expiry date

REF Catalogue number



Consult instructions for use

GTIN Global Trade Item Number



Biological risk

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