REF 5005102 TECHNOCLOT® PT Owren Capillary Control Set

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RUO

TECHNOCLOT® PT Owren Capillary Control Set - English

INTENDED USE

TECHNOCLOT® PT Owren Capillary Control Set is used for accuracy and precision control of TECHNOCLOT® PT Owren manual test using capillary blood as samples.

SUMMARY

TECHNOCLOT® PT Owren Capillary Control Set consists of normal and anticoagulated plasmas.
These controls can be used to determine the accuracy in the normal and abnormal ranges of coagulation activity.
Precision control, i.e. the recording of the day to day variation, is an important procedure in coagulation testing.

REAGENTS

Normal plasma is prepared from selected citrated plasma donations of healthy donors. The clotting activity is normally distributed. Thereby the "average" presence of all coagulation factors and inhibitors is secured.
Abnormal plasma is prepared from plasma of samples stabilized of long-term oral anticoagulant therapy. Therefore the factors of the prothrombine complex (II, VII, IX and X) have the same coagulation activity as plasma from samples on oral anticoagulant therapy. The PIVKA inhibitors (Proteins induced by Vitamin K Absence) are present in this control plasma as in sample plasma. Plasmas contain stabilizers but no preservatives.

mL	Reagent	Description
1	Capillary Control N	Plasma derived from normal samples
1	Capillary Control AK	Plasma derived from anticoagulated samples
2 x 1	Distilled water	
2 x 1	$CaCl_2$	Calcium chloride solution (17mM)

Material required (not supplied with the kit)
- Pipettes
- Calibration Plasma and reagents
  - REF 5005100 TECHNOCLOT® PT Owren Capillary Calibration Set
  - REF 5005032 TECHNOCLOT® PT Owren manual 10 x 4 mL
  - REF 5005037 TECHNOCLOT® PT Owren manual 10 x 10 mL

Warning and precautions

- For research use only
- This control set is intended for use by personnel trained in laboratory procedures and universal precautions for the use of chemicals and potentially biohazardous substances.
- 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.
- Control plasmas are made from human blood and any individual plasma involved in the procedure is HbsAg, HIV 1/2 Ab and HCV-Ab-negative as tested by FDA approved methods. However, all human blood products should be handled as potentially infectious material.
- 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: (Attention: Stability before addition of Calcium Chloride)
After the addition of Calcium Chloride (17mM), Plasma must be tested **immediately**!

18...25°C	+2…8°C	-20°C
4 hours	8 hours	1 month

The vials can be frozen only once.

TEST PROCEDURE

Preparation and performance of the test

- All reagents including distilled water, Calcium Chloride and reagent have to reach room temperature (18…25°C) before use.
- Open the control vials and reconstitute the contents in 1ml of distilled water by carefully rotating the vial until the product is completely reconstituted (avoid foaming). Allow them to stand for 10 minutes at room temperature before use. For standardising tests a reconstitution time of 30 minutes is recommended. Invert to mix before use (avoid foaming).
- During this time, reconstitute the TECHNOCLOT® PT Owren manual following the instructions in the package insert
- Pipette 250µL aliquots of TECHNOCLOT® PT Owren manual reagent into the clotting tube and prewarm at 37°C for at **least 3 minutes**.
- Test one control at a time as the addition of calcium chloride initiates the clotting. This should be done as follow:
  - Add 1mL of enclosed Calcium Chloride (17mM) to the 1mL reconstituted control vial.
  - Mix contents thoroughly.
  - **Immediately** add 25µL into the clotting tube containing the pre-warmed TECHNOCLOT® PT Owren manual reagent and start the timer simultaneously.
  - Note the seconds measured.
- Repeat the above described steps for the other control.

ANALYSIS RESULTS

The figures in the table are only applicable to the indicated lot number of TECHNOCLOT® PT Owren Capillary Control Set and the method has to adhere strictly as prescribed for the respective reagent.

Standardisation

The INR's for TECHNOCLOT® PT Owren Capillary Control Set are determined according to WHO (WHO_TRS_889_A3_1999) guidelines by Technoclone and/or by external quality assessment.

LITERATURE

Please contact Technoclone or your local distributor.

SYMBOLS KEY

	Manufacturer		
	Storage temperature	RUO	For research use only
	Expiry date	LOT	Lot
	Consult instructions for use	REF	Catalogue number

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