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TECHNOCLOT® LA Screen
TECHNOCLOT® LA Confirm
For research use only

GB

REF 5343012	TECHNOCLOT® LA Screen	5 x 2 mL
REF 5343016	TECHNOCLOT® LA Confirm	5 x 1 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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TECHNOCLOT® LA Screen
TECHNOCLOT® LA Confirm

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PRODUCT DESCRIPTION

INTENDEND USE

TECHNOCLOT® LA Screen and TECHNOCLOT® LA Confirm are simplified DRVVT reagents for detection of Lupus Anticoagulants (LA) in one-stage clotting tests.
TECHNOCLOT® LA Screen is a simplified DRVV reagent to screen for the presence of Lupus Anticoagulants.
TECHNOCLOT® LA Confirm is a phospholipids rich DRVV reagent for the specific correction of Lupus Anticoagulants.

LAs are auto antibodies against negatively charged phospholipids or complexes of phospholipids with either beta-2-glycoprotein 1 or clotting factors such as prothrombin. They occur in various clinical conditions, especially autoimmune diseases and are now considered to be a significant risk factor in samples with otherwise unexplained thrombosis and are often present in women who have recurrent foetal loss. LA have traditionally been detected using phospholipid responsive clotting tests, such as the activated partial thromboplastin time (aPTT), kaolin clotting time (KCT) and DRVVT where they have an anticoagulant effect.

TEST PRINCIPLE

Russell's viper venom present in TECHNOCLOT® LA Screen initiate plasma clotting by directly activating factor X. LA antibodies prolong the TECHNOCLOT® LA Screen clotting time.

TECHNOCLOT® LA Confirm is similar to TECHNOCLOT® LA Screen but contains a high phospholipid concentration. The extra phospholipid counteracts the LA antibody and largely corrects the clot time.

DRVV tests "bypass" factor VII of the extrinsic pathway and the contact and antihaemophilic factors of the intrinsic pathway. Therefore TECHNOCLOT® LA Screen is more specific for LA than aPTTs as they are not affected by contact factor abnormalities or by factor FVIII deficiencies or antibodies. They have been a number of tests developed based on phospholipid correction however none have been as convenient to use as TECHNOCLOT® LA Confirm subsequent to TECHNOCLOT® LA Screen.

Mixing tests may be useful to exclude factor II, V and X deficiencies, which may prolong TECHNOCLOT® LA Screen and TECHNOCLOT® LA Confirm results. Mixing normal plasma with test plasma replenishes any factors deficient in the test plasma. If the mixing test is still prolonged, it indicates that an inhibitor (such as LA) is present in the test plasma.

COMPOSITION

TECHNOCLOT® LA Screen and TECHNOCLOT® LA Confirm contain Russell's viper venom, phospholipids anti heparin agents, calcium, buffers, stabilizers, sodium azide and dyes.

MATERIAL REQUIRED (not supplied with the kit)

- Distilled water - Pipettes Controls:

REF	5343010	Lupus Inhibitor Plasma positive	2 x 1 mL
REF	5343019	Lupus Inhibitor Plasma positive	5 x 1 mL
REF	5002040	Coagulation Control N (normal)	5 x 1 mL
REF	5343022	Platelet Poor Plasma (negative)	5 x 2 mL

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 bio safety regulations in force and must be disposed of in the same way as hospital waste.

STABILITY AND STORAGE

The reagents may be used up to the expiry date given on the label when stored unopened at +2…8°C. Stability of the reagents after reconstitution:

+37°C	+20...25°C	+12°C (Ceveron)	+2...8°C	-20°C
8 hours	24 hours	24 hours	48 hours	1 months

TEST PROCEDURE

PREPARATION OF REAGENT

- Reconstitute with the volume of distilled water stated on the vial. Mix well by inversion to ensure complete re-suspension of the lyophilized material. Allow the dissolved reagent to stand for 30 minutes by carefully rotating the vial before use.

PREPARATION OF PLASMA

Plasma preparation: Mix 9 volumes of venous blood and 1 volume of sodium citrate (0.11 mol/L) and centrifuge for 15 minutes at a RCF of 2500 (corresponding to DIN 58905). Transfer the plasma to a clean plastic tube and centrifuge for a further 15 minutes to obtain platelet poor plasma. The plasma should be stored at room temperature and be tested within 4 hours. Shelf life at –20°C: 6 months.

PERFORMANCE OF THE TEST (MANUAL METHOD)

1. Pre-warm a slight excess of TECHNOCLOT® LA Screen or TECHNOCLOT® LA Confirm reagent at +37°C in a reagent reservoir, wallowing for 200 µl per test.
2. Dispense 200 µl of test plasma into a glass test tube and warm for 1 minute at +37°C
3. Add 200 µl of pre-warmed reagent to the plasma and time from the moment of reagent addition to a clotting end point.
4. Repeat for duplicate test values and report the average of these as the result.

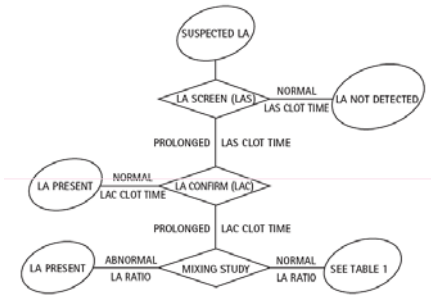
CEVERON

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 sheets supersedes the information in this instruction for use. Please consult the instruction manual of the Ceveron® alpha.

ANALYSES RESULTS

INTERPRETATION OF THE RESULTS

For each new lot of TECHNOCLOT® LA Screen and TECHNOCLOT® LA Confirm kit a new Normal Range should be determined.
If the TECHNOCLOT® LA Screen clotting time is within the normal range no further testing for LA may be necessary. If the TECHNOCLOT® LA Screen clotting time result is more than 20% longer than pooled platelet depleted normal plasma the result should be considered abnormal and investigated further:



The final result is expressed as a ratio of the clotting times of TECHNOCLOT® LA Screen divided by TECHNOCLOT® LA Confirm.

$$\textbf{LA Ratio} = \frac{\text{TECHNOCLOT® LA Screen clotting time}}{\text{TECHNOCLOT® LA Confirm clotting time}}$$

or as

$$\textbf{Normalized LA Ratio} = \frac{\text{LA Ratio Sample}}{\text{LA Ratio Normal Plasma}}$$

Mixing tests:
If results are borderline, mixing studies may be used to correct for hidden defects in the sample and clarify the presence of LA. These tests should be carried out on a 50:50 mixture of test plasma and platelet depleted normal plasma using the standard test procedure.

Table 1: Combination of mixing and confirmatory tests

TECHNOCLOT® LA Screen Clotting time		TECHNOCLOT® LA Confirm Clotting time		Intepretation
Sample Plasma	Mix- Sample + Normal	Sample Plasma	Mix- Sample + Normal	
N	N	N	N	LA not detected
ABN	ABN	N	N	LA probably present
ABN	N	ABN	N	Possible factor deficiency/OAT exclude by further investigation
ABN	ABN	ABN	N	Possible factor deficiency exclude by further investigation
ABN	ABN	ABN	ABN	Exclude other inhibitor by further investigation

QUALITY CONTROL

Each laboratory should determine its own acceptable control values and normal range. Lupus Inhibitor Plasma and Coagulation Control N must be tested at the same time as sample plasma.

LIMITATION AND INTERFERENCES

Samples containing clots and those with abnormal haematocrits should be discarded. Jaundiced, lipemic and haemolysed specimens should be tested by manual techniques as some photo-electric instruments give false results.
Commercially available normal quality control plasmas with unspecified levels of citrate and platelets are not recommended for use in mixing studies.
For comparative studies TECHNOCLOT® LA Screen and TECHNOCLOT® LA Confirm tests should be performed at the same time.
LA assays based on different properties appear to be more or less sensitive to certain subgroups of LAs. Therefore at least two screening assays, based on different properties, should be performed the possibility of LA is excluded.
Heparin levels up to 1 unit/ml have no effect due to the presence of a neutralizing agent in both LA Screen and LA Confirm.

REFERENCE RANGE

Normal ranges for TECHNOCLOT® LA Screen of 31-44 seconds and for TECHNOCLOT® LA Confirm of 30-38 were obtained using a manual tilt-tube method with samples collected from 26 healthy individuals aged 18 to 55 years. The ratio was in the range 0.8 – 1.2. These results should be used as a guide only.

APPLICATIONS FOR INSTRUMENTS

Application Sheets are available from Technoclone or your local distributor upon request.

PERFORMANCE CHARACTERISTICS

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

PRECISION

Reproducibility was determined in series and day to day. The following results were obtained:

	Intra assay		Inter assay	
	TECHNOCLOT® LA Screen	TECHNOCLOT® LA Confirm	TECHNOCLOT® LA Screen	TECHNOCLOT® LA Confirm
n	12	12	12	12
MV	83.42	38.51	75.78 sec	37.54 sec
SD	1.33	2.05	1.72	1.91
CV (%)	1.59	5.32	2.26	5.10

SENSITIVITY

TECHNOCLOT® LA Screen and TECHNOCLOT® LA Confirm has demonstrated a high sensitivity to LA positive plasmas. 29 plasmas with confirmed diagnosis of LA were tested with the kit and were found positive.

SPECIFICITY

TECHNOCLOT® LA Screen and TECHNOCLOT® LA Confirm have also shown a high specificity. 60 non Lupus plasma samples were tested and all gave negative results with TECHNOCLOT® LA Screen and TECHNOCLOT® LA Confirm.

LITERATURE

Please contact Technoclone or your local distributor.