






Lupus Inhibitor Plasma

For research use only



| | | | |
|-----|---------|----------------------------|----------|
| REF | 5343010 | Lupus Inhibitor Plasma | 2 x 1 mL |
| REF | 5343019 | Lupus Inhibitor Plasma | 5 x 1 mL |
| REF | 5343021 | Lupus Inhibitor Plasma Low | 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 |
| | | | |



PRODUCT DESCRIPTION

INTENDED USE

Lupus Inhibitor Plasma and Lupus Inhibitor Plasma Low can be used as a positive control for the Lupus Inhibitor Tests and the TECHNOCLOT® LA Screen and Confirm dRVVT assay.

COMPOSITION

Lupus Inhibitor Plasma and Lupus Inhibitor Plasma Low are prepared from selected lupus inhibitor plasma strongly and low positive in most Lupus Inhibitor screening and confirmatory assays. Lupus Inhibitor Plasma contains stabilizers but no bactericide additives.

MATERIAL REQUIRED (not supplied with the kit)

- Pipette
- Distilled water
- Required Lupus Tests

REF 5343005 Lupus Anticoagulant Test 6 tests

REF 5279025 CaCl₂ solution 50 mmol/L 100 mL

REF 5343012 TECHNOCLOT® LA Screen 5x2 mL

REF 5343016 TECHNOCLOT® LA Confirm 5x1 mL

- Required negative control

REF 5343022 Platelet Poor Plasma 5x2 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 biosafety regulations in force and must be disposed of in the same way as hospital waste.
- Each single donor plasma and each lot of Lupus Inhibitor Plasma are tested and found negative for HBSAg, HIV 1/2 A b and HCV Ab. However, universal precautions (treating all human source materials as if potentially infectious) should be exercised.

STABILITY AND STORAGE

The expiry date printed on the labels applies to storage of the unopened bottles at +2...8 °C.

Stability after reconstitution:

| | | |
|------------------|---------|---------|
| RT* (Ceveron **) | 2...8°C | -20°C |
| 1 day | 3 days | 1 month |

The vials can be only frozen once.

Upon storage, caps should be screwed tightly.

* = room temperature

** = in the Ceveron® alpha in the respective control area in the sample tray

TEST PROCEDURE

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

PREPARATION AND PERFORMANCE OF THE TEST

- Open the vial carefully and reconstitute the vial in 1 mL of distilled water by carefully rotating the vial (avoid frothing).
- Allow the reconstituted Lupus Inhibitor Plasma to stand for 10 minutes at room temperature before use.
- Treat the reconstituted plasma as a citrated sample according to the instructions of the respective test.

ANALYSES RESULTS

EVALUATION OF THE RESULTS

By using the Lupus Anticoagulant Test the coagulation times are evaluated both on the basis of the graph shape (1) and a numerical index (LCA-index) (2).

To produce the graph the various coagulation times of the samples determined are plotted on graph paper.

y-axis: coagulation time in sec.

x-axis: Reagent C (0%), mixture (50%), test plasma (100%)

A typical curve is shown in figure 1 as an example.

In addition the lupus anticoagulant can be determined numerically using the LCA index which is calculated by the formula:

$$LCA \text{ index} = \frac{(b-c)}{a} \times 100$$

a = clotting time of sample's plasma

b = clotting time of sample's plasma mixed with Reagent C

c = clotting time of Reagent C

The presence of lupus inhibitor is characterised by the LCA index value of **above < 15** for the Lupus Inhibitor Plasma and for the Lupus Inhibitor Low Plasma. A convex curve means an additional confirmation of the test results.

The LCA Index found should be compared to the value indicated on the vial label or lot specific batch table of the Lupus Inhibitor Plasma and Lupus Inhibitor Plasma Low.

By using the TECHNOCLOT® LA Screen and Confirm dRVVT assay please refer to the values for LA screen, LA confirm and LA Ratio stated in the lot specific batch table.

STANDARDIZATION

No international standard is available for the standardization of Lupus Inhibitor tests. The Lupus Inhibitor documentation is based on studies testing plasma samples from normal subjects and plasma samples with lupus inhibitor. A house reference batch is established in order to avoid batch-to-batch variation.

LIMITATION OF THE TEST

The expected LCA index value is provided on the vial label and is generated for each lot of control material. These values are provided as a guideline only e.g. depending on the analyzer or coagulometer used.

PERFORMANCE CHARACTERISTICS

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

PRECISION

Reproducibility was determined with Technoclot LA Screen and Confirm and with Lupus Anticoagulant Test. The following results were obtained using results in seconds:

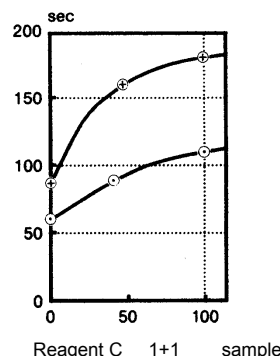
| | Lupus Inhibitor Plasma | | Lupus Inhibitor Plasma Low | | Platelet Poor Plasma | |
|-----------------|------------------------|-------------------|----------------------------|-------------------|----------------------|-------------------|
| | Intra-assay (CV%) | Inter-assay (CV%) | Intra-assay (CV%) | Inter-assay (CV%) | Intra-assay (CV%) | Inter-assay (CV%) |
| LA Screen | 2,2 | 3,8 | 0,7 | 2,9 | 3,1 | 5,4 |
| LA Confirm | 0,6 | 2,3 | 0,9 | 2,3 | 1,6 | 3,1 |
| Lupus Test PL 2 | 0,9 | 2,5 | 1,4 | 1,9 | 1,6 | 1,2 |
| Lupus Test PL 1 | 2,1 | 1,0 | 1,5 | 1,6 | 0,7 | 0,4 |

LITERATURE

- (1) T. EXNER, K. A. RICKARD, H. KRONENBERG: A Sensitive Test Demonstrating Lupus Anticoagulant and its Behavioural Patterns. Brit. J. Haem. 40 (1978); 143
- (2) E. ROSNER, R. PAUZNER, A. LUSKY, M. MODAN, A. MANY: Detection and Quantitative Evaluation of Lupus Circulating Anticoagulant Activity. Thrombos. Haemostas. 57 (1987); 144
- (3) D. A. TRIPLETT: Screening for the Lupus Anticoagulant. Research in Clin. and Lab. 19 (1989); 379

Figure 1

Lupus Inhibitor



Clotting time performed with: ⊕ Phospholipid conc. 1
 ⊙ Phospholipid conc. 2