

PlasmaCon LA

ABNORMAL COAGULATION CONTROL PLASMA FOR LUPUS ANTICOAGULANTS



INTENDED USE

PlasmaCon LA is intended for use as an LA positive, abnormal quality control plasma to monitor the performance of diagnostic assays, performed in professional clinical laboratories, for the presence of lupus anticoagulants in citrated plasma.

SUMMARY

Modern quality control practices require that test procedures be monitored with test materials of known performance for, or concentration of, those constituents to be assayed. **PlasmaCon LA** is a lyophilized Lupus Anticoagulant (LA) positive plasma suitable for use as a quality control plasma for *in vitro* diagnostic assays in the clinical coagulation laboratory sensitive for the presence of LA

PRINCIPLE OF THE PROCEDURE

PlasmaCon LA can be used in all testing in the same manner as any citrated plasma sample. **PlasmaCon LA** can be used to monitor testing variables in laboratory QC systems (e.g. instrumentation, reagents and technique) for assays sensitive to the presence of LA.

REAGENT

FOR IN-VITRO DIAGNOSTIC USE ONLY

Catalog No: 150-200. 10 x 0.5 mL vials

Catalog No: 150-201. 10 x 1.0 mL vials

PlasmaCon LA is prepared from citrated plasma(s) from known LA donors and normal donors. The plasma control contains buffer and stabilizers and is lyophilized. **PlasmaCon LA** does not contain any preservatives.

WARNING: Potential Biohazard: **PlasmaCon LA** has been found negative for Hepatitis B Antigen (HBsAg) and antibodies to HCV and HIV by FDA licensed tests. However, the control should be handled with the same precautions as those observed when handling potentially infectious patient plasmas.

Preparation for Use: **PlasmaCon LA** should be reconstituted with the volume of deionized or distilled water indicated on the vial label. Swirl gently; do not shake. Allow the plasma to stand for 15 minutes at room temperature to insure complete dissolution before use.

Storage and Stability: Unopened **PlasmaCon LA** is stable until the expiration date shown on the label when stored at 2-8°C. Reconstituted plasma is stable (e.g., less than a 10% shift in the baseline values) for 8 hours when stored capped at 2-8°C or 4 hours at room temperature (23-25°C).

INSTRUMENTS

PlasmaCon LA may be used as a control when performing LA tests on any mechanical or photo-optical coagulation instrument in conjunction with suitable commercial reagents.

PROCEDURE

PlasmaCon LA is treated in the same manner as the unknown specimen in accordance with the instructions outlined in the procedure used in the laboratory.

LIMITATIONS

PlasmaCon LA, like any control plasma, is subject to the limitations of the assay system. Quality control of coagulation assays involves multiple components, including reagents, pipettes, distilled water, buffers and instruments. Each laboratory should establish a Quality Control program that includes both normal and abnormal control plasmas. If any of the controls are outside the reference ranges established by the laboratory, then the assay should be considered invalid, no patient results should be reported, and the assay and controls investigated to determine and correct the source of the problem(s).

EXPECTED VALUES

The results obtained with **PlasmaCon LA** depend on several factors including instrumentation, types of reagents and laboratory-to-laboratory variation. Results for **PlasmaCon LA** should fall above the normal reference ranges established by the laboratory for the LA sensitive tests of interest

Laboratories should establish the mean values and expected control ranges for their particular laboratory's instrument-reagent system for each new lot of control, upon instrument service, or a change in test procedure.

PERFORMANCE CHARACTERISTICS

Precision: Precision estimates of **PlasmaCon LA** with multiple lots of r2 Diagnostics' LupoTek Detectin VL (an LA screening reagent) and LupoTek Correctin VL (an LA confirmatory reagent) were determined in a two run per day, twenty day exercise on a Stago STA Compact analyzer as described in the CLSI guideline EP5-A2 "Evaluation of Precision Performance of Quantitative Measurement Methods; Approve Guideline, 2nd Edition, 2004". The mean clotting times and average precision results as %CV were:

Reagent	Mean clot time, seconds	Repeatability Imprecision	Total Imprecision
Detectin VL	83.7	1.4%	3.3%
Correctin VL	39.7	1.2%	2.8%

These performance results should be considered illustrative only. Each laboratory should establish their own control ranges and Quality Control program for their reagents and instruments according to the appropriate Clinical Laboratory Improvement Amendment (CLIA) regulations and Clinical Laboratory Standards Institute (CLSI) guidelines.