

PlasmaCon L-2

HIGH-LEVEL ABNORMAL COAGULATION CONTROL PLASMA



INTENDED USE

PlasmaCon L-2 is a human lyophilized plasma control intended for use as a high level abnormal control with citrated plasma to monitor the performance of the prothrombin time (PT) and activated partial thromboplastin time (APTT) tests.

SUMMARY

PT and APTT tests are used to monitor the efficacy of anticoagulant therapy and to screen for defects in the hemostatic pathways. The PT is sensitive to deficiencies in the extrinsic and common pathways of the coagulation system. The APTT test is sensitive to deficiencies in the intrinsic and common pathways.

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.

PRINCIPLE OF THE PROCEDURE

PlasmaCon L-2 is treated in the same manner as an unknown specimen. Please refer to the appropriate package insert for PT or APTT kits.

REAGENT

FOR IN-VITRO DIAGNOSTIC USE ONLY

Ingredients: **PlasmaCon L-2** is prepared from a pool of citrated plasma from normal donors and then processed to partially deplete the clotting factors II, VII, IX, and X. The plasma control is buffered with HEPES and lyophilized.

10 vials **PlasmaCon L-2** - 1 mL, 100 determinations

PlasmaCon L-2 contains no preservatives.

WARNING: Potential Biohazard: **PlasmaCon L-2** has been found negative for Hepatitis B Antigen (HBsAg) and antibodies to HCV and HIV by FDA licensed tests. The control should be handled with the same precautions observed when handling potentially infectious patient plasmas.

Preparation for Use: Reconstitute **PlasmaCon L-2** with 1.0 mL of deionized or distilled water. Swirl gently; do not shake. Allow control to stand for 15 minutes at room temperature to insure complete dissolution before use.

Storage and Stability: The lyophilized **PlasmaCon L-2** is stable for up to one year when stored at 2 to 8°C. Refer to the vial label for actual expiration date. After reconstitution, the control is stable for 8 hours stored at 2 to 8°C. Keep covered.

INSTRUMENTS

PlasmaCon L-2 may be used as a high-level abnormal control plasma when performing PT and APTT tests by manual method or using any

mechanical or photo-optical coagulation instrument in conjunction with suitable commercial reagents.

PROCEDURE

PlasmaCon L-2 should be treated in the same manner as the unknown specimen in accordance with the instructions outlined in the procedure used in the laboratory.

LIMITATIONS

PlasmaCon L-2 is an abnormal control to be used in PT and APTT test systems. Reference range is a function of individual populations. Each institution should determine its own reference range on a statistically valid sample of its patient population.

EXPECTED VALUES

The results obtained with **PlasmaCon L-2** depend on several factors associated with instrumentation, type of reagents and laboratory-to-laboratory variation. **PlasmaCon L-2** Coagulation Control Plasma has been standardized to give a PT of approximately 2.0 to 3.0 times normal with the Phosphoplastin RL reagent and to give a prolonged APTT with the Phospholin ES reagent. Typical results for r² Diagnostics' reagents on the ACL3000+ are:

	Mean (seconds)	Range for ± 3 SD
Phosphoplastin RL (PT)	52.5	46.8-58.2 seconds
Phospholin ES (APTT)	73.4	73.1-73.7 seconds

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 studies were performed to establish Within Run and Between Run CVs according to the following procedure developed under NCCLS EP15-A User Demonstration of Performance for Precision and Accuracy; Approved Guidelines. For Within Run, 10 vials of each sample were pooled, tested, and recorded in duplicate or triplicate. For Between Run, 2 vials of each sample were pooled, tested in duplicate or triplicate, and recorded each day for 5 days. Assays were performed on the ACL3000+, MLA1000c, Dade BCS, ACL Advance, and Stago STA using various PT and APTT reagents as indicated below. A %CV of less than 15% was accepted. A summary of the statistical data for precision is shown below.

Using r² Diagnostics Phosphoplastin RL (PT) and Phospholin ES (APTT)

PlasmaCon L-2 ACL3000+	Within Run PT	Within Run APTT	Between Run PT	Between Run APTT
n	30	30	15	15
Mean	55.0 sec	75.8 sec	52.5 sec	73.4 sec
SD	1.0	0.9	1.9	0.1
%CV	1.7	1.1	3.6	0.2

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Using r^2 Diagnostics Phosphoplastin RL (PT) and Phospholin ES (APTT)

PlasmaCon L-2 MLA1000c	Within Run PT	Within Run APTT	Between Run PT	Between Run APTT
n	30	30	15	15
Mean	57.4 sec	90.1 sec	53.4 sec	85.1 sec
SD	3.1	7.2	4.1	3.4
%CV	5.3	8.0	7.7	4.0

Using Dade-Behring Thromborel STM (PT) and Pathromtin SLTM (APTT)

PlasmaCon L-2 Dade BCS	Within Run PT	Within Run APTT	Between Run PT	Between Run APTT
n	30	30	15	15
Mean	53.1 sec	99.6 sec	55.3 sec	99.4 sec
SD	0.23	0.66	1.2	0.4
%CV	0.44	0.66	2.3	0.4

Using Stago Neoplastine CI+TM (PT) and Auto PTTTM (APTT)

PlasmaCon L-2 Stago STA	Within Run PT	Within Run APTT	Between Run PT	Between Run APTT
n	30	30	15	15
Mean	61.5 sec	63.0 sec	62.5 sec	57.8 sec
SD	0.4	0.2	0.5	1.7
%CV	0.7	0.4	0.8	3.0

Using r^2 Diagnostics Phosphoplastin RL (PT) and Phospholin ES (APTT)

PlasmaCon L-2 ACL Advance	Within Run PT	Within Run APTT	Between Run PT	Between Run APTT
n	30	30	15	15
Mean	36.3 sec	61.3 sec	38.0 sec	59.9 sec
SD	0.36	0.25	5.1	0.8
%CV	1.00	0.41	13.5	1.4

