

PlasmaCon N

NORMAL COAGULATION CONTROL PLASMA



INTENDED USE

PlasmaCon N is a human lyophilized plasma control intended for use as a normal 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 N can be used in all testing in the same manner as any citrated plasma sample. **PlasmaCon N** can be used to monitor testing variables in laboratory QC systems (e.g. instrumentation, reagents and technique).

REAGENT

FOR IN-VITRO DIAGNOSTIC USE ONLY

Ingredients: **PlasmaCon N** is prepared from a pool of citrated plasma from normal donors with normal coagulation parameters. The plasma control is buffered with HEPES and lyophilized.

10 vials **PlasmaCon N**- 1 mL, 100 determinations

PlasmaCon N contains no preservatives.

WARNING: Potential Biohazard: **PlasmaCon N** 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 N** should be reconstituted 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 N** 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 N may be used as a control when performing PT and APTT tests on any mechanical or photo-optical coagulation instrument in conjunction with suitable commercial reagents.

PROCEDURE

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

LIMITATIONS

Although **PlasmaCon N** is a normal control, the times or results obtained on testing should not be used as the normal reference range for a particular patient population. 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 N** depend on several factors including instrumentation, types of reagents and laboratory-to-laboratory variation. PT and APTT results for **PlasmaCon N** should fall within the reference ranges stated in the package inserts of these test kits. Typical results for r² Diagnostics' reagents on the ACL3000+ are:

	Mean (seconds)	Range for ± 3 SD
Phosphoplastin RL (PT)	12.7	12.4-13.0 seconds
Phospholin ES (APTT)	29.5	28.9-31.1 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 CLSI 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.

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

<i>PlasmaCon N ACL3000+</i>	<i>Within Run PT</i>	<i>Within Run APTT</i>	<i>Between Run PT</i>	<i>Between Run APTT</i>
n	30	30	15	15
Mean	12.7 sec	30.0 sec	12.7 sec	29.5 sec
SD	0.1	0.3	0.1	0.2
%CV	0.6	1.0	1.0	0.7

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

<i>PlasmaCon N MLA1000c</i>	<i>Within Run PT</i>	<i>Within Run APTT</i>	<i>Between Run PT</i>	<i>Between Run APTT</i>
n	30	30	15	15
Mean	14.5 sec	34.8 sec	14.3 sec	35.9
SD	0.1	1.4	0.1	0.4
%CV	0.5	4.1	0.5	1.1

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

<i>PlasmaCon N Dade BCS</i>	<i>Within Run PT</i>	<i>Within Run APTT</i>	<i>Between Run PT</i>	<i>Between Run APTT</i>
n	30	30	15	15
Mean	13.0 sec	36.5 sec	13.1	36.3
SD	0.14	0.18	0.1	0.3
%CV	1.05	0.51	0.5	0.8

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

<i>PlasmaCon N Stago STA</i>	<i>Within Run PT</i>	<i>Within Run APTT</i>	<i>Between Run PT</i>	<i>Between Run APTT</i>
n	30	30	15	15
Mean	13.5 sec	31.8 sec	13.7 sec	31.0
SD	0.1	0.4	0.1	0.9
%CV	0.9	1.4	0.4	2.9

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

<i>PlasmaCon N ACL Advance</i>	<i>Within Run PT</i>	<i>Within Run APTT</i>	<i>Between Run PT</i>	<i>Between Run APTT</i>
n	30	30	15	15
Mean	12.4 sec	29.9 sec	12.8 sec	31.5
SD	0.07	0.17	0.3	0.5
%CV	0.56	0.56	2.5	1.6

