

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: Control Plasma-LMW Heparin	PRODUCT # : 823492
EXP. DATE: 2006-12	LOT # : N0940622
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 823500/823492

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
A. Control Plasma, Low: LMW Heparin (H01337)					
Mean value	0.33	0.42	IU/vial	0.34	PASS
Intra series CV (n=60)	-	10	%	9.1	PASS
Inter bottle CV (n=12)	-	10	%	7.7	PASS
Total % CV (n=12)	-	7	%	6.1	PASS

B. Control Plasma, High, LMW Heparin (H01346)					
Mean value	0.64	0.84	IU/vial	0.78	PASS
Intra series CV (n=60)	-	5	%	2.7	PASS
Inter bottle CV (n=12)	-	5	%	2.3	PASS
Total % CV (n=12)	-	7	%	2.3	PASS

C. Control Plasma LMW Heparin Kit					
Slope	-1.063	-0.523	-	-0.765	PASS
r ²	0.98	-	-	1.000	PASS
Control (low) recovery	0.27	0.41	IU/mL	0.32	PASS
Control (high) recovery	0.71	0.85	IU/mL	0.77	PASS

Kit Components:

Name	Lot Number	Exp. Date	Mfg. Date
Control Plasma, Low, LMW Heparin	N0840513	2007-02	2004-08
Control Plasma, High, LMW Heparin	N0649820	2006-12	2004-06

THE PLASMA MATERIAL USED IN THE MANUFACTURE OF THIS PRODUCT HAS BEEN TESTED AND FOUND NON-REACTIVE FOR HIV, HBsAg AND ANTI-HCV.

We hereby certify that the above product(s):

- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;

PREPARED BY: *Raquel Bustamante*

DATE: 09/08/04

APPROVAL SIGNATURE: *John Facciola*

DATE: 09/08/04