CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	Control Plasma-LMW Heparin	PRODUCT # :	823492
EXP. DATE:	2007-05	LOT # :	N1142011
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823500/823492

TEST DESCRIPTION		SPECIFICATIONS			RESULTS	DISPOSITION
A. Control Plasma, Low: LMW Heparin (H01337)		**MIN**	**MAX**	**UNITS**		**PASS/FAIL**
Mean value		0.33	0.42	IU/vial	0.33	PASS
Intra series CV (n=60)		-	10	%	7.2	PASS
Inter bottle CV (n=12)		-	10	%	4.2	PASS
Total % CV (n=12)		-	7	%	4.2	PASS
B. Control Plasma, High, LMW Heparin (H01346)						
Mean value		0.64	0.84	IU/vial	0.75	PASS
Intra series CV (n=60)		-	5	%	4.4	PASS
Inter bottle CV (n=12)		-	5	%	3.3	PASS
Total % CV (n=12)		-	7	%	3.2	PASS
C. Control Plasma LMW Heparin Kit						
Slope		-1.063	-0.523	-	-0.739	PASS
r^2		0.98	-	-	0.999	PASS
Control (low) recovery		0.26	0.40	IU/mL	0.28	PASS
Control (high) recovery		0.68	0.82	IU/mL	0.69	PASS

Kit Components:

Name	Lot Number	Exp. Date	Mfg. Date
Control Plasma, Low, LMW Heparin	N1141937	2007-05	2004-11
Control Plasma, High, LMW Heparin	N1141938	2007-05	2004-11

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;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: *Raquel Bustamante* DATE: 12/07/04

APPROVAL SIGNATURE: *John Facciola* DATE: 12/07/04

Form QCM 823500/823492-1, Rev. 10/03