

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

PRODUCT: Control Plasma-LMW Heparin	PRODUCT # : 823492
EXP. DATE: 2006-10	LOT # : N0548782
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 823500/823492

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
<b>A. Control Plasma, Low: LMW Heparin (H01337)</b>					
Mean value	0.33	0.42	IU/vial	0.34	PASS
Intra series CV (n=60)	-	10	%	7.5	PASS
Inter bottle CV (n=12)	-	10	%	4.1	PASS
Total % CV (n=12)	-	7	%	5	PASS

<b>B. Control Plasma, High, LMW Heparin (H01346)</b>					
Mean value	0.64	0.84	IU/vial	0.70	PASS
Intra series CV (n=60)	-	5	%	3.3	PASS
Inter bottle CV (n=12)	-	5	%	2.9	PASS
Total % CV (n=12)	-	7	%	2.8	PASS

<b>C. Control Plasma LMW Heparin Kit</b>					
Slope	-1.063	-0.523	-	-0.766	PASS
r <sup>2</sup>	0.98	-	-	1.000	PASS
Control (low) recovery	0.27	0.41	IU/mL	0.37	PASS
Control (high) recovery	0.63	0.77	IU/mL	0.74	PASS

**Kit Components:**

Name	Lot Number	Exp. Date	Mfg. Date
Control Plasma, Low, LMW Heparin	N0448749	2006-10	2004-04
Control Plasma, High, LMW Heparin	N0448750	2006-10	2004-04

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:                     05/11/04                    

APPROVAL SIGNATURE:                     *John Facciola*                    

DATE:                     05/11/04