

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: Control Plasma-LMW Heparin	PRODUCT #: 823492
EXP. DATE: 2018-12	LOT #: N0663698
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 823492/823500

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
A. Control Plasma, Low: LMW Heparin (H01337)					PASS/FAIL
Mean value	0.33	0.42	IU/vial	0.35	PASS
Intra series CV (n=60)	-	10	%	5	PASS

B. Control Plasma, High, LMW Heparin (H01346)					
Mean value	0.64	0.84	IU/vial	0.73	PASS
Intra series CV (n=60)	-	5	%	4	PASS

Kit Components:

Name	Lot Number	Exp. Date	Mfg. Date
Control Plasma, Low, LMW Heparin	N0663695	2018-12	July7,2016
Control Plasma, High, LMW Heparin	N0663696	2018-12	July7,2016

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: NPATEL P.M. Patel

DATE: July27,2016 July 27, 2016

APPROVAL SIGNATURE: DTENCZA D. Tenca

DATE: July27,2016 July 27, 2016