

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

PRODUCT:	Control Plasma-LMW Heparin	PRODUCT #:	823492
EXP. DATE:	2017-05	LOT #:	N1243858
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823492/823500

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. Control Plasma, Low: LMW Heparin (H01337)</b>					
Mean value	0.33	0.42	IU/vial	0.35	PASS
Intra series CV (n=60)	-	10	%	8	PASS

<b>B. Control Plasma, High, LMW Heparin (H01346)</b>					
Mean value	0.64	0.84	IU/vial	0.74	PASS
Intra series CV (n=60)	-	5	%	4	PASS

**Kit Components:**

Name	Lot Number	Exp. Date	Mfg. Date
Control Plasma, Low, LMW Heparin	N1143458	2017-05	12/8/2014
Control Plasma, High, LMW Heparin	N1143459	2017-05	12/8/2014

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 N.m. Patel DATE: 1/13/2015 1:13:15

APPROVAL SIGNATURE: DTENCZA D. Jancza DATE: 1/13/2015 1/13/15