

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: Calibration Plasma-LMW Heparin	PRODUCT #: 82350063
EXP. DATE: 2017-02	LOT #: N0942222
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 823492/823500

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. Cal. Plasma 2 LMW Heparin (H01364)					
Mean value	0.37	0.53	IU/vial	0.41	PASS
Intra series CV (n=80)	-	10	%	8	PASS

B. Cal Plasma 3 LMW Heparin (H01373)					
Mean value	0.75	0.88	IU/vial	0.80	PASS
Intra series CV (n=60)	-	5	%	3	PASS

Kit Components:

Name	Lot Number	Exp. Date	Mfg. Date
Calibration plasma 1 LMW Heparin	N0841803	2017-02	8/22/2014
Calibration plasma 2 LMW Heparin	N0841804	2017-02	8/22/2014
Calibration plasma 3 LMW Heparin	N0841805	2017-02	8/22/2014

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: 9/11/2014 9-11-14

APPROVAL SIGNATURE: DTENCZA P. Dencza DATE: 9/11/2014 9/11/14