

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: Calibration Plasma-LMW Heparin	PRODUCT # : 82350063
EXP. DATE: 2019-09	LOT # : N0378866
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 823492/823500

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
A. Cal. Plasma 2 LMW Heparin (H01364)					PASS/FAIL
Mean value	0.37	0.53	IU/vial	0.44	PASS
Intra series CV (n=60)	-	10	%	4	PASS

B. Cal Plasma 3 LMW Heparin (H01373)					
Mean value	0.75	0.86	IU/vial	0.80	PASS
Intra series CV (n=60)	-	5	%	2	PASS

Kit Components:

Name	Lot Number	Exp. Date	Mfg. Date
Calibration plasma 1 LMW Heparin	N0378713	2019-09	3/29/2017
Calibration plasma 2 LMW Heparin	N0378722	2019-09	3/29/2017
Calibration plasma 3 LMW Heparin	N0378723	2019-09	3/29/2017

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: 4/24/2017 4-24-17

APPROVAL SIGNATURE: DTENCZA D. Encza DATE: 4/24/2017 4/24/17