

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

PRODUCT:	Calibration Plasma-LMW Heparin	PRODUCT #:	82350063
EXP. DATE:	2017-10	LOT #:	N0958580
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823492/823500

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
<b>A. Cal. Plasma 2 LMW Heparin (H01364)</b>	MIN	MAX			PASS/FAIL
Mean value	0.37	0.63	IU/vial	0.41	PASS
Intra series CV (n=60)	-	10	%	5	PASS

<b>B. Cal Plasma 3 LMW Heparin (H01373)</b>					
Mean value	0.75	0.86	IU/vial	0.78	PASS
Intra series CV (n=60)	-	5	%	3	PASS

**Kit Components:**

Name	Lot Number	Exp. Date	Mfg. Date
Calibration plasma 1 LMW Heparin	N0456116	2017-10	5/4/2015
Calibration plasma 2 LMW Heparin	N0958437	2018-03	9/22/2015
Calibration plasma 3 LMW Heparin	N0958438	2018-03	9/22/2015

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: 9/29/2015 9-29-15

APPROVAL SIGNATURE: DTENCZA P. Dencza DATE: 9/29/2015 9/29/15

Form QCM0082350063/0082349263-2, Rev. 08/10

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