

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME:	Calibration Plasma-LMW Heparin	EXPIRATION DATE:	2021-07
PRODUCT NUMBER:	82350063		
LOT NUMBER:	N0193157		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
A. Control Plasma, Low: LMW Heparin (H01337)					
Mean value	0.37	0.53	IU/vial	0.37	PASS
Intra series CV (n=60)	-	10	%	6	PASS

B. Control Plasma, High, LMW Heparin (H01346)					
Mean value	0.75	0.86	IU/vial	0.77	PASS
Intra series CV (n=60)	-	5	%	4	PASS

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: Nehal Patel N.M. Patel
 PRINT SIGNATURE

DATE: 2/6/2019 2-6-19

TITLE Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Hays Debra Lee Hays
 PRINT SIGNATURE

DATE: 2/6/2019 2-6-19

TITLE Technical Supervisor

QCM0082350063/82349263-2, Rev. 00