

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME:	Control Plasma-LMW Heparin	EXPIRATION DATE:	2021-05
PRODUCT NUMBER:	82349263		
LOT NUMBER:	N1182072		

TEST DESCRIPTION	SPECIFICATIONS			UNITS	RESULTS	DISPOSITION
	MIN	MAX				
A. Control Plasma, Low: LMW Heparin (H01337)						
Mean value	0.33	0.42		IU/vial	0.36	PASS
Intra series CV (n=60)	-	10		%	6	PASS
B. Control Plasma, High, LMW Heparin (H01346)						
Mean value	0.64	0.84		IU/vial	0.70	PASS
Intra series CV (n=60)	-	5		%	5	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: 12/11/2018 *12-11-18*

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Donna Tencza *D. Tencza* PRINT SIGNATURE

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