

CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation
Laboratory
A Werfen Company

PRODUCT NAME:	Control Plasma-LMW Heparin	EXPIRATION DATE:	2020-11
PRODUCT NUMBER:	82349263		
LOT NUMBER:	N0588133		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
A. Control Plasma, Low: LMW Heparin (H01337)					
Mean value	0.33	0.42	IU/vial	0.34	PASS
Intra series CV (n=60)	-	10	%	5	PASS

B. Control Plasma, High, LMW Heparin (H01346)					
Mean value	0.64	0.84	IU/vial	0.69	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: M. Oettinger  DATE: 6/20/2018 6-20-18
 PRINT SIGNATURE

TITLE QC Analyst

APPROVAL SIGNATURE D. Tencza  DATE: 6/20/2018 6/20/18
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TITLE Senior QC Analyst

QCM0082350063/82349263-1, Rev. 01