CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation Laboratory
A Werfer Company

PRODUCT NAME:	Control Plasma-LMW Heparin	EXPIRATION DATE:	2023-11
PRODUCT NUMBER:	82349263		
LOT NUMBER:	N0512819		

TEST DESCRIPTION		SPECIFICATIONS			RESULTS	DISPOSITION
A. Control Plasma, Low: LMW Heparin		MIN	MAX	UNITS		PASS/FAIL
Mean value		0.33	0.42	IU/vial	0.36	PASS
Intra series CV (n=60)		-	10	%	7	PASS
B. Control Plasma, High, LMW Heparin						
Mean value		0.64	0.84	IU/vial	0.70	PASS
Intra series CV (n=60)		-	5	%	4	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
Control Plasma LMW Heparin, Low	N0512816	1 mL
Control Plasma LMW Heparin, High	N0512818	1 mL

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 DATE: 5/26/2021 5-26-21
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TITLE Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz Debra Lee Harz DATE: 5/26/2021 5/26/21
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