

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

**Instrumentation  
Laboratory**  
A Werfen Company

PRODUCT NAME:	Control Plasma-LMW Heparin	EXPIRATION DATE:	2023-02
PRODUCT NUMBER:	82349263		
LOT NUMBER:	N0806394		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
<b>A. Control Plasma, Low: LMW Heparin</b>					<b>PASS/FAIL</b>
Mean value	0.33	0.42	IU/vial	0.37	PASS
Intra series CV (n=60)	-	10	%	8	PASS

<b>B. Control Plasma, High, LMW Heparin</b>					
Mean value	0.64	0.84	IU/vial	0.77	PASS
Intra series CV (n=60)	-	5	%	5	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
Control Plasma LMW Heparin, Low	N0806390	1 mL
Control Plasma LMW Heparin, High	N0806391	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: 9/3/2020 *9-3-20*  
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TITLE Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz* DATE: 9/3/2020 *9/3/20*  
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