

CERTIFICATE OF ANALYSIS



PRODUCT NAME:	Calibration Plasma-LMW Heparin	EXPIRATION DATE:	2023-03
PRODUCT NUMBER:	82350063		
LOT NUMBER:	N0907577		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		
A. Control Plasma, Low: LMW Heparin					
Mean value	0.37	0.53	IU/vial	0.41	PASS
Intra series CV (n=60)	-	10	%	5	PASS

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

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
Calibration Plasma LMW Heparin 1	N0907573	1 mL
Calibration Plasma LMW Heparin 2	N0907574	1 mL
Calibration Plasma LMW Heparin 3	N0907576	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*
 PRINT SIGNATURE

DATE: 10/20/2020 *10-20-20*

TITLE Senior QC Analyst

APPROVAL SIGNATURE: Donna Tenza *Donna Tenza*
 PRINT SIGNATURE

DATE: 10/20/2020 *10/20/20*

TITLE Senior QC Analyst