

CERTIFICATE OF ANALYSIS

CHROMOGENIX *werfen*

PRODUCT NAME:	COAMATIC HEPARIN	EXP DATE:	2027-03-31
PRODUCT NUMBER:	00082339363		
LOT NUMBER:	N0351183		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa					
ACTIVITY	31.5	38.5	nkU/vial	37.6	PASS
STANDARD CURVE (r^2)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.7	73.7	nkU/vial	70.3	PASS

B. S-2732, FOR COAMATIC HEPARIN					
SUBSTRATE CONCENTRATION	14.3	15.7	ng/vial	14.4	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS

C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.191	PASS
r^2	0.985	--	--	0.997	PASS

D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.193	PASS
r^2	0.985	--	--	0.998	PASS

KIT COMPONENTS:			
NAME	LOT NUMBER	VOLUME	
COAMATIC HEPARIN FACTOR Xa	N0351180	1 mL	
COAMATIC HEPARIN S-2732	N0351181	2 mL	

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;

PREPARED BY: Brianna Randazzo *Brianna Randazzo* DATE: 5/7/2025
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N. Patel* DATE: 5-7-25
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TITLE: Senior Group Leader