

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME	COAMATIC HEPARIN	EXP DATE	2026-05-31
PRODUCT NUMBER	82339363		
LOT NUMBER	N0643667		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa					
pH	7.9	8.1	pH	7.9	PASS
ACTIVITY	31.5	38.5	nkatal/vial	34.2	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	69.8	76.0	nkatal/vial	74.5	PASS

B. S-2732, FOR COAMATIC HEPARIN					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	15.1	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS

C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.298	PASS
r ²	0.985	--	--	0.995	PASS

D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.296	PASS
r ²	0.985	--	--	0.987	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COAMATIC HEPARIN FACTOR Xa	N0643666	1 mL
COAMATIC HEPARIN S-2732	N0543004	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,
 - meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked

PREPARED BY: Monika Skowronska *Monika Skowronska* DATE: 8/9/2024 *8-9-24*
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N. M. Patel* DATE: 8/9/2024 *8.9.24*
 PRINT SIGNATURE

TITLE: Senior Group Leader