

**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			
<b>A. FACTOR Xa</b>					<b>PASS/FAIL</b>
pH	7.9	8.1	pH	7.9	PASS
ACTIVITY	31.5	38.5	nkat/vial	34.2	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	68.8	76.0	nkat/vial	74.5	PASS

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

<b>C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP</b>					
SLOPE	-0.351	-0.103	--	-0.298	PASS
r <sup>2</sup>	0.985	--	--	0.995	PASS

<b>D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP</b>					
SLOPE	-0.335	-0.114	--	-0.296	PASS
r <sup>2</sup>	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*  
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TITLE: Senior Group Leader