

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

**Instrumentation  
Laboratory**  
A Werfen Company

PRODUCT NAME:	COAMATIC HEPARIN	EXP DATE:	2023-04
PRODUCT NUMBER:	82339363		
LOT NUMBER:	N0412385		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. FACTOR Xa</b>					
pH	7.9	8.1	pH	7.9	PASS
ACTIVITY	31.5	38.5	nkat/vial	34.0	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	65.7	72.7	nkat/vial	66.8	PASS

<b>B. S-2732, FOR COAMATIC HEPARIN</b>					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	15.2	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.2	PASS

<b>C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP</b>					
SLOPE	-0.351	-0.103	--	-0.186	PASS
r <sup>2</sup>	0.985	--	--	0.998	PASS

<b>D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP</b>					
SLOPE	-0.336	-0.114	--	-0.176	PASS
r <sup>2</sup>	0.985	--	--	0.997	PASS

<b>KIT COMPONENTS:</b>			
NAME	LOT NUMBER	VOLUME	
COAMATIC HEPARIN FACTOR Xa	N0412384	1 mL	
COAMATIC HEPARIN S-2732	N0412239	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: Maria Oettinger *Maria Oettinger* DATE: 5-17-21  
 PRINT SIGNATURE

TITLE: QC Analyst III

APPROVAL SIGNATURE: Debra Harz *Debra Harz* DATE: 5-17-21  
 PRINT SIGNATURE

TITLE: QC Technical Supervisor