

CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation
Laboratory

A Werfen Company

PRODUCT NAME:	COAMATIC HEPARIN	EXP DATE:	2021-03
PRODUCT NUMBER:	82339363		
LOT NUMBER:	N0394320		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
A. FACTOR Xa					
pH	7.9	8.1	pH	7.9	PASS
ACTIVITY	31.5	38.5	nkat/vial	34.8	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	0.998	PASS
CONTROL RECOVERY	66.0	73.0	nkat/vial	69.8	PASS

B. S-2732, FOR COAMATIC HEPARIN					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.7	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.195	PASS
r ²	0.985	--	--	0.996	PASS

D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.173	PASS
r ²	0.985	--	--	0.997	PASS

KIT COMPONENTS:		
NAME	LOT NUMBER	VOLUME
COAMATIC HEPARIN FACTOR Xa	N0394317	1 mL
COAMATIC HEPARIN S-2732	N0394319	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: 4/3/2019 4-3-19
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TITLE: QC Analyst III

APPROVAL SIGNATURE: D. Tencza D. Tencza DATE: 4/3/2019 4/3/19
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TITLE: Senior QC Analyst