CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation Laboratory
A Werfen Company

PRODUCT NAME:	COAMATIC HEPARIN	EXP DATE:	2023-03
PRODUCT NUMBER:	82339363		
LOT NUMBER:	N0311286		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		PASS/FAIL
A. FACTOR Xa					
pH	7.9	8.1	pH	7.9	PASS
ACTIVITY	31.5	38.5	nkat/vial	36.8	PASS
STANDARD CURVE (r^2)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	65.7	72.7	nkat/vial	71.3	PASS
B. S-2732, FOR COAMATIC HEPARIN					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.5	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS
C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.1971	PASS
r^2	0.985	--	--	0.994	PASS
D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.1751	PASS
r^2	0.985	--	--	0.996	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COAMATIC HEPARIN FACTOR Xa	N0412059	1 mL
COAMATIC HEPARIN S-2732	N0311055	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 (PRINT) Maria Oettinger (SIGNATURE) DATE: 4-28-21

TITLE: QC Analyst III

APPROVAL SIGNATURE: Debra Harz (PRINT) Debra Harz (SIGNATURE) DATE: 4/28/21

TITLE: QC Technical Supervisor