CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation Laboratory
A Werfen Company

PRODUCT NAME:	COAMATIC HEPARIN	EXP DATE:	2021-07
PRODUCT NUMBER:	82339363		
LOT NUMBER:	N0897707		

TEST DESCRIPTION	SPECIFICATIONS MIN	SPECIFICATIONS MAX	UNITS	RESULTS	DISPOSITION PASS/FAIL
A. FACTOR Xa					
pH	7.9	8.1	pH	8.0	PASS
ACTIVITY	31.5	38.5	nkat/vial	35.5	PASS
STANDARD CURVE (r^2)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.0	73.0	nkat/vial	71.6	PASS
B. S-2732, FOR COAMATIC HEPARIN					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.9	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS
C. COAMATIC HEPARIN KIT - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.201	PASS
r^2	0.985	--	--	0.998	PASS
D. COAMATIC HEPARIN KIT - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.185	PASS
r^2	0.985	--	--	0.996	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COAMATIC HEPARIN FACTOR Xa	N0897563	1 mL
COAMATIC HEPARIN S-2732	N0797524	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: 8-20-19

TITLE: QC Analyst III

APPROVAL SIGNATURE: Debra Lee Harz (PRINT) Debra Lee Harz (SIGNATURE) DATE: 8/20/19

TITLE: QC Technical Supervisor

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