CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COAMATIC HEPARIN	PRODUCT # :	82339363
EXP. DATE:	2016-03	LOT # :	N0440080
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823393

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		PASS/FAIL
A. FACTOR Xa (H01382)					
pH	7.9	8.1	pH	7.9	PASS
ACTIVITY	31.5	38.5	nkat/vial	34.2	PASS
STANDARD CURVE (r^2)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.1	73.1	nkat/vial	69.8	PASS
B. S-2732, FOR COAMATIC HEPARIN (H01391)					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.4	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS
C. COAMATIC HEPARIN KIT (082339363) - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.186	PASS
r^2	0.985	--	--	0.991	PASS
D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.173	PASS
r^2	0.985	--	--	0.996	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
Factor Xa	N0640717	2016-06	1 ml (x 2)
S-2732	N0349296	2016-03	2 ml (x 2)

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: N. M. Patel DATE: 6.24.14

APPROVAL SIGNATURE: P. Renga DATE: 6-24-14

Form QCM0082339363-1, Rev. 08/10

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