

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COAMATIC HEPARIN	PRODUCT #: 82339363
EXP. DATE: 2019-02	LOT #: N0278188
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 823393

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa (H01382)					
pH	7.9	8.1	pH	8.0	PASS
ACTIVITY	31.5	38.5	nkat/vial	33.6	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	-0.999	PASS
CONTROL RECOVERY	67.8	75.0	nkat/vial	68.9	PASS

B. S-2732, FOR COAMATIC HEPARIN (H01391)					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.8	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

C. COAMATIC HEPARIN KIT (082339363) - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.185	PASS
r ²	0.985	--	--	0.996	PASS

D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.176	PASS
r ²	0.985	--	--	0.994	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
Factor Xa	N0278187	2019-02	1 ml (x 2)
S-2732	N0278182	2019-02	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: NPATEL N.m. Patel

3-13-17
DATE: 3/13/2017

APPROVAL SIGNATURE: DTENCZA J. Dencza

3/13/17
DATE: 3/13/2017