

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COAMATIC HEPARIN	PRODUCT #: 82339363
EXP. DATE: 2016-07	LOT #: N0741451
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	7.9	PASS
ACTIVITY	31.5	38.5	nkat/vial	35.9	PASS
STANDARD CURVE (r^2)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.1	73.1	nkat/vial	69.5	PASS

B. S-2732, FOR COAMATIC HEPARIN (H01391)					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.9	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS

C. COAMATIC HEPARIN KIT (082339363) - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.189	PASS
r^2	0.985	--	--	0.992	PASS

D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.189	PASS
r^2	0.985	--	--	0.996	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
Factor Xa	N0741450	2016-07	1 ml (x 2)
S-2732	N0741335	2016-07	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. Patel N.M. Patel

DATE: 8-5-14
8/5/2014

APPROVAL SIGNATURE: D. Tencza P. Anza

DATE: 8/5/14
8/5/2014

Form QCM0082339363-1, Rev. 08/10