

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: <u>COAMATIC HEPARIN</u>	PRODUCT #: <u>82339363</u>
EXP. DATE: <u>2018-10</u>	LOT #: <u>N1065536</u>
VENDOR: <u>INSTRUMENTATION LABORATORY</u>	ASSAYED PER QCM: <u>823393</u>

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	35.0	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	67.5	74.6	nkat/vial	68.9	PASS

B. S-2732, FOR COAMATIC HEPARIN (H01391)					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.6	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

C. COAMATIC HEPARIN KIT (082339363) - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.213	PASS
r ²	0.985	--	--	0.998	PASS

D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.200	PASS
r ²	0.985	--	--	0.985	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
Factor Xa	N1065533	2018-10	1 ml (x 2)
S-2732	N1065535	2018-10	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: VPATEL N.M. Patel

10-27-16
DATE: 10/27/2016

APPROVAL SIGNATURE: DTENCZA D. Tenca

10/27/16
DATE: 10/27/2016