

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COAMATIC HEPARIN	PRODUCT #: 82339363
EXP. DATE: 2020-01	LOT #: N0285547
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	33.1	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	67.8	75.0	nkat/vial	70.3	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	--	-0.201	PASS
r ²	0.985	--	--	0.995	PASS

D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.183	PASS
r ²	0.985	--	--	0.993	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
Factor Xa	N0285546	2020-02	1 ml (x 2)
S-2732	N0185370	2020-01	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

DATE: 2/26/2018 2-26-18

APPROVAL SIGNATURE: DTENCZA J. Dencza

DATE: 2/26/2018 2/26/18