

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COAMATIC HEPARIN	PRODUCT # :	82339363
EXP. DATE:	2020-05	LOT # :	N0587747
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	33.5	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	67.8	75.0	nkat/vial	70.8	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	--	-0.183	PASS
r ²	0.985	--	--	0.993	PASS

D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.194	PASS
r ²	0.985	--	--	0.998	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
Factor Xa	N0587742	2020-05	1 ml (x 2)
S-2732	N0587746	2020-05	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: ⁶⁻¹⁻¹⁸ 6/1/2018

APPROVAL SIGNATURE: DTENCZA D. Tenca

DATE: 6/1/2018 ^{6/1/18}