

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

PRODUCT:	COAMATIC HEPARIN	PRODUCT #:	82339363
EXP. DATE:	2016-10	LOT #:	N1043093
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823393

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. FACTOR Xa (H01382)</b>					
pH	7.9	8.1	pH	7.9	PASS
ACTIVITY	31.5	38.5	nkat/vial	36.0	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	0.999	PASS
CONTROL RECOVERY	66.1	73.1	nkat/vial	71.6	PASS

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

<b>C. COAMATIC HEPARIN KIT (082339363) - LMW HEPARIN ON TOP</b>					
SLOPE	-0.351	-0.103	--	-0.211	PASS
r <sup>2</sup>	0.985	--	--	0.991	PASS

<b>D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP</b>					
SLOPE	-0.336	-0.114	--	-0.198	PASS
r <sup>2</sup>	0.985	--	--	0.991	PASS

**Kit Components:**

Name	Lot Number	Exp. date	Volume
Factor Xa	N1042993	2016-10	1 ml (x 2)
S-2732	N1043092	2016-10	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: MPATEL D.M. Patel

DATE: 11-14-14  
11/14/2014

APPROVAL SIGNATURE: DTENCZA P. Denga

DATE: 11/14/2014

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