

## CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

PRODUCT: <u>COAMATIC HEPARIN</u>	PRODUCT #: <u>82339363</u>
EXP. DATE: <u>2017-08</u>	LOT #: <u>N0858205</u>
VENDOR: <u>INSTRUMENTATION LABORATORY</u>	ASSAYED PER QCM: <u>823393</u>

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	37.1	PASS
STANDARD CURVE ( $r^2$ )	0.990	1.000	--	0.999	PASS
CONTROL RECOVERY	67.5	74.6	nkat/vial	72.2	PASS

<b>B. S-2732, FOR COAMATIC HEPARIN (H01391)</b>					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.3	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	--	-0.225	PASS
$r^2$	0.985	--	--	0.994	PASS

<b>D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP</b>					
SLOPE	-0.336	-0.114	--	-0.218	PASS
$r^2$	0.985	--	--	0.988*	PASS

**Kit Components:**

Name	Lot Number	Exp. date	Volume
Factor Xa	N0853053	2017-08	1 ml (x 2)
S-2732	N0857824	2017-08	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:                     Maria Dettlinger                    

DATE:                     9-9-15                    

APPROVAL SIGNATURE:                     P. Danga                    

DATE:                     9/9/15