

CERTIFICATE OF ANALYSIS

CHROMOGENIX

**Instrumentation
Laboratory**

A Werfen Company

PRODUCT NAME:	COAMATIC HEPARIN	EXP DATE:	2020-08
PRODUCT NUMBER:	82339363		
LOT NUMBER:	N0889828		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
A. FACTOR Xa (H01382)					
pH	7.9	8.1	pH	7.9	PASS
ACTIVITY	31.5	38.5	nkat/vial	32.5	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.0	73.0	nkat/vial	68.8	PASS

B. S-2732, FOR COAMATIC HEPARIN (H01391)					
SUBSTRATE CONCENTRATION	14.3	15.7	mg/vial	14.5	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

C. COAMATIC HEPARIN KIT (082339363) - LMW HEPARIN ON TOP					
SLOPE	-0.351	-0.103	--	-0.232	PASS
r ²	0.985	--	--	0.994	PASS

D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP					
SLOPE	-0.336	-0.114	--	-0.202	PASS
r ²	0.985	--	--	0.987	PASS

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: M.Oettinger *M. Oettinger* DATE: 8/29/2018 *8-29-18*
 PRINT SIGNATURE

TITLE: QC Analyst III

APPROVAL SIGNATURE: D.Tencza *D. Tencza* DATE: 8/29/2018 *8/29/18*
 PRINT SIGNATURE

TITLE: Senior QC Analyst