

**CERTIFICATE OF ANALYSIS**

# **CHROMOGENIX**

PRODUCT: COAMATIC Protein C	Recording of Results	82209863
EXP. DATE: 2018-12	Lot #:	N1266756
VENDOR: INSTRUMENTATION LABORATORY	Assayed per QCM:	822098/822106/49730500

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. Protein C Activator (H00749)</b>					
ACTIVITY VS. REFERENCE LOT	90	110	%	101	PASS
SLOPE	0.0010	0.0015	--	0.0013	PASS
INTERCEPT	--	0.010	--	0.004	PASS
REGRESSION COEFFICIENT	0.990	--	--	0.999	PASS
<u>CONTROL PLASMAS:</u>					
NORMAL	95	125	%	108	PASS
SPECIAL TEST LEVEL I	49	69	%	58	PASS
SPECIAL TEST LEVEL II	23	43	%	31	PASS

<b>B. S-2366/ I-2581 For Coamatic Protein C (H00163)</b>					
SUBSTRATE CONCENTRATION	5.4	6.6	mg/vial	6.0	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS

<b>C. COAMATIC PROTEIN C KIT (0822098)</b>					
SLOPE	0.0010	0.0015	--	0.0012	PASS
INTERCEPT	--	0.010	--	0.003	PASS
REGRESSION COEFFICIENT	0.990	--	--	1.000	PASS
<u>CONTROL PLASMA</u>					
NORMAL	95	125	%	106	PASS
SPECIAL TEST LEVEL I	49	69	%	57	PASS
SPECIAL TEST LEVEL II	23	43	%	32	PASS

<b>KIT COMPONENTS :</b>			
NAME	LOT NUMBER	EXP. DATE	VOLUME
Protein C Activator	N1266753	2018-12	2 ml (x 2)
S-2366/I-2581	N1266749	2018-12	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:

*M. Oettinger*

DATE: 12/23/2016

APPROVAL SIGNATURE:

*D. Tencza*

DATE: 1/3/2017