

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COAMATIC Protein C	Recording of Results	82209863
EXP. DATE: 2015-05	Lot #:	N0534637
VENDOR: INSTRUMENTATION LABORATORY	Assayed per QCM:	822098/822106/49730500

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
A. Protein C Activator (H00749)					
ACTIVITY VS. REFERENCE LOT	90	110	%	102	PASS
SLOPE	0.0010	0.0015	--	0.0014	PASS
INTERCEPT	--	0.010	--	0.003	PASS
REGRESSION COEFFICIENT	0.990	--	--	0.999	PASS
CONTROL PLASMAS:					
NORMAL	87	117	%	103	PASS
SPECIAL TEST LEVEL I	50	70	%	58	PASS
SPECIAL TEST LEVEL II	19	39	%	26	PASS

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

C. COAMATIC PROTEIN C KIT (0822098)					
SLOPE	0.0010	0.0015	--	0.0014	PASS
INTERCEPT	--	0.010	--	0.003	PASS
REGRESSION COEFFICIENT	0.990	--	--	1.000	PASS
CONTROL PLASMA					
NORMAL	87	117	%	99	PASS
SPECIAL TEST LEVEL I	50	70	%	57	PASS
SPECIAL TEST LEVEL II	19	39	%	25	PASS

KIT COMPONENTS :			
NAME	LOT NUMBER	EXP. DATE	VOLUME
Protein C Activator	N0534636	2015-05	2 ml (x 2)
S-2366/I-2581	N0534565	2015-05	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:

N. Patel N. m. Patel

DATE: 6/21/2013

6-21-13

APPROVAL SIGNATURE:

D. Tencza D. Tencza

DATE: 6/21/2013

6/21/13