

CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation
Laboratory
A Werfen Company

PRODUCT NAME:	COAMATIC Protein C	EXPIRATION DATE:	2021-04
PRODUCT NUMBER:	82209863		
LOT	N0595686		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. Protein C Activator					
ACTIVITY VS. REFERENCE LOT	90	110	%	98	PASS
SLOPE	0.0010	0.0015	—	0.0011	PASS
INTERCEPT	—	0.010	—	0.002	PASS
REGRESSION COEFFICIENT	0.990	—	—	0.999	PASS
<u>CONTROL PLASMAS:</u>					
NORMAL	85	115	%	98	PASS
SPECIAL TEST LEVEL I	48	68	%	57	PASS
SPECIAL TEST LEVEL II	20	40	%	28	PASS

B. S-2366/ I-2581 For Coamatic Protein C					
SUBSTRATE CONCENTRATION	5.4	6.6	mg/vial	5.9	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.2	PASS

C. COAMATIC PROTEIN C KIT					
SLOPE	0.0010	0.0015	—	0.0011	PASS
INTERCEPT	—	0.010	—	0.004	PASS
REGRESSION COEFFICIENT	0.990	—	—	0.999	PASS
<u>CONTROL PLASMA</u>					
NORMAL	85	115	%	99	PASS
SPECIAL TEST LEVEL I	48	68	%	51	PASS
SPECIAL TEST LEVEL II	20	40	%	27	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.

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COAMATIC PROTEIN C S-2366	N0495504	7.2 mL
COAMATIC PROTEIN C ACTIVATOR	N0595685	7.2 mL

PREPARED BY:

Nehal Patel

N.M. Patel

DATE: 5/30/2019

5-30-19

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SIGNATURE

TITLE: Senior QC Analyst

APPROVAL SIGNATURE:

Debra Lee Harz

Debra Lee Harz

DATE: 5/30/2019

5/30/19

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TITLE: QC Technical Supervisor