

CERTIFICATE OF ANALYSIS

CHROMOGENIX



**Instrumentation
Laboratory**

A Werfen Company

PRODUCT NAME:	COAMATIC Protein C	EXPIRATION DATE:	2022-02
PRODUCT NUMBER:	82209863		
LOT	N0202250		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. Protein C Activator					
ACTIVITY VS. REFERENCE LOT	90	110	%	103	PASS
SLOPE	0.0010	0.0015	--	0.0013	PASS
INTERCEPT	--	0.010	--	0.003	PASS
REGRESSION COEFFICIENT	0.990	--	--	1.000	PASS
CONTROL PLASMAS:					
NORMAL	84	114	%	100	PASS
SPECIAL TEST LEVEL I	47	67	%	52	PASS
SPECIAL TEST LEVEL II	20	40	%	27	PASS

B. S-2366/ I-2581 For Coamatic Protein C					
SUBSTRATE CONCENTRATION	5.4	6.6	mg/vial	5.8	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS

C. COAMATIC PROTEIN C KIT					
SLOPE	0.0010	0.0015	--	0.0012	PASS
INTERCEPT	--	0.010	--	0.003	PASS
REGRESSION COEFFICIENT	0.990	--	--	0.999	PASS
CONTROL PLASMA					
NORMAL	84	114	%	101	PASS
SPECIAL TEST LEVEL I	47	67	%	52	PASS
SPECIAL TEST LEVEL II	20	40	%	30	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	N0202123	7.2 mL
COAMATIC PROTEIN C ACTIVATOR	N0202249	7.2 mL

PREPARED BY:

Bhumi Vasoya

Bhumi Vasoya

DATE:

03/16/2020

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SIGNATURE

TITLE: Qc Analyst-I

APPROVAL SIGNATURE:

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2c Tech Supervisor