

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

**Instrumentation  
Laboratory**  
A Werfen Company

PRODUCT NAME:	COAMATIC Protein C	EXPIRATION DATE:	2023-05
PRODUCT NUMBER:	82209863		
LOT	N0513175		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. Protein C Activator</b>					
ACTIVITY VS. REFERENCE LOT	90	110	%	94	PASS
SLOPE	0.0010	0.0015	--	0.0010	PASS
INTERCEPT	--	0.010	--	0.003	PASS
REGRESSION COEFFICIENT	0.990	--	--	0.999	PASS
CONTROL PLASMAS:					
NORMAL	87	117	%	100	PASS
SPECIAL TEST LEVEL I	50	70	%	58	PASS
SPECIAL TEST LEVEL II	21	41	%	29	PASS

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

<b>C. COAMATIC PROTEIN C KIT</b>					
SLOPE	0.0010	0.0015	--	0.0010	PASS
INTERCEPT	--	0.010	--	0.002	PASS
REGRESSION COEFFICIENT	0.990	--	--	1.000	PASS
CONTROL PLASMA					
NORMAL	87	117	%	114	PASS
SPECIAL TEST LEVEL I	50	70	%	67	PASS
SPECIAL TEST LEVEL II	21	41	%	36	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	N0513169	7.2 mL
COAMATIC PROTEIN C ACTIVATOR	N0513172	7.2 mL

PREPARED BY: Nehal Patel *N.M. Patel* DATE: 6/10/2021 *6-10-21*  
 PRINT SIGNATURE

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz* DATE: 6/10/2021 *6-10-21*  
 PRINT SIGNATURE

TITLE: QC Technical Supervisor