

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COAMATIC ANTITHROMBIN	PRODUCT #: 82199163
EXP. DATE: 2017-11	LOT #: N0556571
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 821991/49730501

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa 29 nkat (H00132)					
ACTIVITY	26	32	nkat/vial	27	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	68.9	73.1	nkat/vial	69.7	PASS

B. S-2765 8.0 mg (H00015)					
SUBSTRATE CONCENTRATION	7.6	8.6	mg/vial	8.0	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

C. 8.2 pH BUFFER (H00149)					
APPEARANCE	Clear, colorless solution		--	PASS	PASS
pH	8.1	8.3	pH	8.2	PASS

D. COAMATIC ANTITHROMBIN KIT TEST (821991)					
SLOPE	-0.0024	-0.0034	--	-0.0031	PASS
INTERCEPT	0.40	0.60	--	0.48	PASS
STANDARD CURVE (r ²)	0.99	1.00	--	0.999	PASS
NORMAL CONTROL PLASMA	81	111	%	97	PASS
SPECIAL TEST LEVEL 1	43	63	%	52	PASS
SPECIAL TEST LEVEL 2	20	40	%	25	PASS

Kit Components :

Name	Lot Number	Exp. date	Volume
Factor Xa 29nkat	N0455905	2018-04	1 ml (x 1)
S-2765 8.0 mg	N0456014	2018-04	2 ml (x 1)
8.2 pH Buffer	N1143452	2017-11	25.5 ml (x 1)

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:

Maria Dettenyer

DATE:

5-27-15

APPROVAL SIGNATURE:

P. Amza

DATE:

5/28/15