

**CERTIFICATE OF ANALYSIS**

# CHROMOGENIX

PRODUCT: <u>COAMATIC ANTITHROMBIN</u>	PRODUCT #: <u>82199163</u>
EXP. DATE: <u>2019-09</u>	LOT #: <u>N1065701</u>
VENDOR: <u>INSTRUMENTATION LABORATORY</u>	ASSAYED PER QCM: <u>821991/49730501</u>

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
<b>A. FACTOR Xa 29 nkat (H00132)</b>					
ACTIVITY	26	32	nkat/vial	30	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	0.999	PASS
CONTROL RECOVERY	68.9	73.1	nkat/vial	69.6	PASS

<b>B. S-2765, 8.0 mg (H00015)</b>					
SUBSTRATE CONCENTRATION	7.6	8.6	mg/vial	7.8	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.0	PASS

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

<b>D. COAMATIC ANTITHROMBIN KIT TEST (821991)</b>					
SLOPE	-0.0024	-0.0034	--	-0.0030	PASS
INTERCEPT	0.40	0.60	--	0.50	PASS
STANDARD CURVE (r <sup>2</sup> )	0.99	1.00	--	0.999	PASS
NORMAL CONTROL PLASMA	81	111	%	99	PASS
SPECIAL TEST LEVEL 1	41	61	%	51	PASS
SPECIAL TEST LEVEL 2	21	41	%	32	PASS

**Kit Components :**

Name	Lot Number	Exp. date	Volume
Factor Xa 29nkat	N0965303	2019-09	1 ml (x 1)
S-2765 8.0 mg	N1065534	2019-10	2 ml (x 1)
8.2 pH Buffer	N0965429	2019-09	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:

Marina Dettlinger

DATE:

10-21-16

APPROVAL SIGNATURE:

Pomdanga

DATE:

10/26/16