

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

PRODUCT: COAMATIC ANTITHROMBIN	PRODUCT #: 82199163
EXP. DATE: 2016-03	LOT #: N0534460
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 821991/49730501

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
<b>A. FACTOR Xa 29 nkat (H00132)</b>					
ACTIVITY	26	32	nkat/vial	29	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	67.5	71.7	nkat/vial	67.5	PASS

<b>B. S-2765.8.0 mg (H00015)</b>					
SUBSTRATE CONCENTRATION	7.6	8.6	mg/vial	7.9	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS

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

<b>D. COAMATIC ANTITHROMBIN KIT TEST (821991)</b>					
SLOPE	-0.0024	-0.0034	--	-0.0033	PASS
INTERCEPT	0.40	0.60	--	0.46	PASS
STANDARD CURVE (r <sup>2</sup> )	0.99	1.00	--	0.999	PASS
NORMAL CONTROL PLASMA	85	115	%	98	PASS
SPECIAL TEST LEVEL 1	45	65	%	51	PASS
SPECIAL TEST LEVEL 2	20	40	%	22	PASS

**Kit Components :**

Name	Lot Number	Exp. date	Volume
Factor Xa 29nkat	N0434103	2016-04	1 ml (x 1)
S-2765 8.0 mg	N0333699	2016-03	2 ml (x 1)
8.2 pH Buffer	N0534459	2016-05	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: M. Oettinger M. Oettinger DATE: 5/30/2013 5-30-13

APPROVAL SIGNATURE: D. Teacza D. Teacza DATE: 5/30/2013 5/30/13