

**CERTIFICATE OF ANALYSIS**

# **CHROMOGENIX**

PRODUCT: COATEST Heparin	PRODUCT #: 25553963
EXP. DATE: 2019-03	LOT #: N1166474
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 255539/49730504

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. FACTOR Xa (650515)</b>					
ACTIVITY	61	81	nkat/vial	73	PASS
STANDARD CURVE (r <sup>2</sup> )	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	67.5	74.6	nkat/vial	72.7	PASS
RESIDUAL MOISTURE	0	5	%	0.2	PASS

<b>B. S-2222, FOR COATEST HEPARIN (654009)</b>					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	15.1	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS
RESIDUAL MOISTURE	0	5	%	0.2	PASS

<b>C. ANTITHROMBIN 10 IU, FOR COATEST HEPARIN (654023)</b>					
ANTITHROMBIN ACTIVITY	9	11	IU/vial	9	PASS

<b>D. NORMAL CONTROL PLASMA (650292)</b>					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0	PASS
<b>STANDARD CURVE:</b>					
regression coefficient (r <sup>2</sup> )	0.99	1.00	--	0.994	PASS
slope	-0.800	-0.500	--	-0.616	PASS
intercept	0.650	1.030	--	0.726	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.359	PASS
APPEARANCE	yellowish-white, lyophilized powder			PASS	PASS

<b>E. BUFFER pH 8.4 CONC., FOR COATEST HEPARIN</b>					
APPEARANCE	clear, colorless solution			PASS	PASS
pH @ 20 - 25°C	8.3	8.5	--	8.5	PASS

<b>F. COATEST HEPARIN KIT</b>					
SLOPE	-0.800	-0.500	--	-0.579	PASS
INTERCEPT	0.650	1.030	--	0.800	PASS
REGRESSION COEFFICIENT (r <sup>2</sup> )	0.99	1.00		0.997	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS

**KIT COMPONENTS :**

NAME	LOT NUMBER	EXP. DATE	VOLUME
FXa	N0965428	2019-03	2 ml (x 1)
S-2222, 15 mg	N1166393	2019-05	4 ml (x 1)
ANTITHROMBIN 10 IU	N1065790	2019-04	1 ml (x 1)
NORMAL CONTROL PLASMA	N1166473	2019-05	1 ml (x 4)
BUFFER pH 8.4	N1166471	2019-05	12 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: NPATEL N.m. Patel DATE: 12/16/2016 12-16-16

APPROVAL SIGNATURE: DTENCZA J. Dencza DATE: 12/16/2016 12/16/16