

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COATEST Heparin	PRODUCT #: 25553963
EXP. DATE: 2016-07	LOT #: N0540425
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 255539/49730504

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. FACTOR Xa (650515)					
ACTIVITY	61	81	nkat/vial	69	PASS
STANDARD CURVE (r ²)	0.990	1.000	-	0.998	PASS
CONTROL RECOVERY	66.1	73.1	nkat/vial	69.0	PASS
RESIDUAL MOISTURE	0	5	%	0.2	PASS

B. S-2222, FOR COATEST HEPARIN (654009)					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	15.3	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS
RESIDUAL MOISTURE	0	5	%	0.3	PASS

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

D. NORMAL CONTROL PLASMA (850292)					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0.04	PASS
STANDARD CURVE:					
regression coefficient (r ²)	0.99	1.00	--	0.996	PASS
slope	-0.800	-0.500	--	-0.625	PASS
intercept	0.650	1.030	--	0.762	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.277	PASS
APPEARANCE	yellowish-white, lyophilized powder			PASS	PASS

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

F. COATEST HEPARIN KIT					
SLOPE	-0.800	-0.500	--	-0.592	PASS
INTERCEPT	0.650	1.030	--	0.743	PASS
REGRESSION COEFFICIENT (r ²)	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	N0540424	2016-11	2 ml (x 1)
S-2222, 15 mg	N0148151	2016-07	4 ml (x 1)
ANTITHROMBIN 10 IU	N0540346	2016-11	1 ml (x 1)
NORMAL CONTROL PLASMA	N0148588	2016-07	1 ml (x 4)
BUFFER pH 8.4	N0349154	2018-09	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:

N. M. Patel

DATE:

6-24-14

APPROVAL SIGNATURE:

J. Longa

DATE:

6-24-14