

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COATEST Heparin	PRODUCT #: 25553963
EXP. DATE: 2017-07	LOT #: N0656828
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 255539/49730504

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
A. FACTOR Xa (650515)					
ACTIVITY	61	81	nkat/vial	74	PASS
STANDARD CURVE (r ²)	0.990	1.000	-	1.000	PASS
CONTROL RECOVERY	67.5	74.6	nkat/vial	70.1	PASS
RESIDUAL MOISTURE	0	5	%	0.2	PASS

B. S-2222, FOR COATEST HEPARIN (654009)					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	14.9	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.1	PASS
RESIDUAL MOISTURE	0	5	%	0.5	PASS

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

D. NORMAL CONTROL PLASMA (650292)					
HEPARIN ANTAGONISTS	0	< 0.10	IU/mL	0.02	PASS
STANDARD CURVE:					
regression coefficient (r ²)	0.99	1.00	--	0.997	PASS
slope	-0.800	-0.500	--	-0.578	PASS
intercept	0.650	1.030	--	0.739	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.6	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.366	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	--	-0.677	PASS
INTERCEPT	0.650	1.030	--	0.698	PASS
REGRESSION COEFFICIENT (r ²)	0.99	1.00	--	0.99	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS

KIT COMPONENTS :			
NAME	LOT NUMBER	EXP. DATE	VOLUME
FXa	N0455725	2017-08	2 ml (x 1)
S-2222, 15 mg	N0455727	2017-07	4 ml (x 1)
ANTITHROMBIN 10 IU	N0455728	2017-08	1 ml (x 1)
NORMAL CONTROL PLASMA	N0455725	2017-07	1 ml (x 4)
BUFFER pH 8.4	N0455729	2017-07	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: 6/10/2015 6:10:15

APPROVAL SIGNATURE: DTENCZA J. Dencza DATE: 6/10/2015 6/10/15

Form QCM 25553963/49730504-1, Rev 01/09