

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COATEST Heparin	PRODUCT #: 25553963
EXP. DATE: 2017-07	LOT #: N0254839
VENDOR: INSTRUMENTATION LABDRATDRY	ASSAYED PER QCM: 255539/49730504

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION PASS/FAIL
	MIN	MAX			
A. FACTDR Xa (650515)					
ACTIVITY	61	81	nkatal/vial	74	PASS
STANDARD CURVE (r ²)	0.990	1.000	-	1.000	PASS
CONTROL RECOVERY	67.5	74.6	nkatal/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. ANTIHROMBIN 10 IU, FOR COATEST HEPARIN (654023)					
ANTIHRMBIN ACTIVITY	9	11	IU/vial	10	PASS

D. NORMAL CONTRL 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	-	-0.576	PASS
Intercept	0.650	1.030	-	0.739	PASS
CONTRL. RECOVERY	0.4	0.6	IU/mL	0.6	PASS
ABSORBANCE AT 405nm	0.00	0.400	-	0.388	PASS
APPEARANCE	yellowish-white, lyophilized powder			PASS	PASS

E. BUFFER pH 6.4 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	LDT NUMBER	EXP DATE	VOLUME
FXa	N0254681	2017-08	2 ml (x 1)
S-2222, 15 mg	N0153981	2017-07	4 ml (x 1)
ANTIHRMBIN 10 IU	N0254837	2017-08	1 ml (x 1)
NORMAL CONTRL PLASMA	N0154024	2017-07	1 ml (x 4)
BUFFER pH 8.4	N0154133	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: MPATEL N.M. Patel DATE: 3/31/2015 3.31.15

APPROVAL SIGNATURE: DTENCZA P. Dencza DATE: 3/31/2015 3/31/15

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