

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COATEST Heparin	PRODUCT # : 25553963
EXP. DATE: 2005-02	LOT # : N0130868
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	70	PASS
STANDARD CURVE (r ²)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.8	71.0	nkat/vial	68.4	PASS
RESIDUAL MOISTURE	0	5	%	0.4	PASS

B. S-2222, FOR COATEST HEPARIN (654009)					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	14.8	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.05	PASS
RESIDUAL MOISTURE	0	5	%	0.3	PASS

C. ANTITHROMBIN 10 IU, FOR COATEST HEPARIN (654023)					
ANTITHROMBIN ACTIVITY	9	11	IU/vial	9.9	PASS
RESIDUAL MOISTURE	0	5	%	2.1	PASS

D. NORMAL CONTROL PLASMA (H01462)					
HEPARIN ANTAGONISTS	0	0.1	IU/mL	0	PASS
STANDARD CURVE:					
regression coefficient (r ²)	0.99	1.00	--	0.99	PASS
slope	-0.800	-0.500	--	-0.639	PASS
intercept	0.650	1.030	--	0.654	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.399	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	--	8.5	PASS

F. COATEST HEPARIN KIT					
SLOPE	-0.800	-0.500	--	-0.719	PASS
INTERCEPT	0.650	1.030	--	0.703	PASS
REGRESSION COEFFICIENT (r ²)	0.99	1.00		0.993	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS

KIT COMPONENTS :

NAME	LOT NUMBER	EXP. DATE	VOLUME
FXa	N1029531	2005-04	2 ml (x 1)
S-2222, 15 mg	N0130793	2005-07	4 ml (x 1)
ANTITHROMBIN 10 IU	N1129887	2005-05	1 ml (x 1)
NORMAL CONTROL PLASMA	N0130740	2005-07	1 ml (x 4)
BUFFER pH 8.4	N0828245	2005-02	12 ml (x 1)

PREPARED BY: *Raquel Bustamante* DATE: 01/30/03

APPROVAL SIGNATURE: *Mike Fader* DATE: 01/30/03