CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST Heparin	PRODUCT # :	25553963
EXP. DATE:	2006-01	LOT # :	N1236484
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	255539/49730504

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	DISPOSITION
	MIN	MAX	UNITS		PASS/FAIL
A. FACTOR Xa (650515)					
ACTIVITY	61	81	nkat/vial	75	PASS
STANDARD CURVE (r^2)	0.990	1.000	--	1.000	PASS
CONTROL RECOVERY	66.1	73.1	nkat/vial	71.6	PASS
RESIDUAL MOISTURE	0	5	%	0.6	PASS
B. S-2222, FOR COATEST HEPARIN (654009)					
SUBSTRATE CONCENTRATION	14.25	16.2	mg/vial	15.1	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.03	PASS
RESIDUAL MOISTURE	0	5	%	1.4	PASS
C. ANTITHROMBIN 10 IU, FOR COATEST HEPARIN (654023)					
ANTITHROMBIN ACTIVITY	9	11	IU/vial	10	PASS
RESIDUAL MOISTURE	0	5	%	0.8	PASS
D. NORMAL CONTROL PLASMA (650292)					
HEPARIN ANTAGONISTS	0	0.1	IU/mL	0.03	PASS
STANDARD CURVE:					
regression coefficient (r^2)	0.99	1.00	--	0.996	PASS
slope	-0.800	-0.500	--	-0.631	PASS
intercept	0.650	1.030	--	0.751	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS
ABSORBANCE AT 405nm	0.00	0.400	--	0.398	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	--	8.3	PASS
F. COATEST HEPARIN KIT					
SLOPE	-0.800	-0.500	--	-0.663	PASS
INTERCEPT	0.650	1.030	--	0.771	PASS
REGRESSION COEFFICIENT (r^2)	0.99	1.00		0.992	PASS
CONTROL RECOVERY	0.4	0.6	IU/mL	0.5	PASS

KIT COMPONENTS :

NAME	LOT NUMBER	EXP.DATE	VOLUME
FXa	N0733808	2006-01	2 ml (x 1)
S-2222, 15 mg	N0733749	2006-01	4 ml (x 1)
ANTITHROMBIN 10 IU	N1236195	2006-05	1 ml (x 1)
NORMAL CONTROL PLASMA	N1236447	2006-06	1 ml (x 4)
BUFFER pH 8.4	N0934894	2006-03	12 ml (x 1)

We hereby certify that the above product(s):

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: *Raquel Bustamante* DATE: 01/13/04

APPROVAL SIGNATURE: *John Facciola* DATE: 01/13/04

Form QCM 25553963, Rev. 12/03