

CHROMOGENIX

PRODUCT:	COAMATIC PLASMIN INHIBITOR	PRODUCT # :	82318763
EXP. DATE:	2005-05	LOT # :	N0633431
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823187/49730502

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. S-2403 (650-591)					
SUBSTRATE CONCENTRATION	7.98	8.82	mg/vial	8.5	PASS
FREE p - NITROANILINE	--	0.5	mol %	0.2	PASS
RESIDUAL MOISTURE	--	5.0	% H ₂ O	0.58	PASS

B. PLASMIN REAGENT (H00908)					
PLASMIN CONTENT	6.4	9.6	nkat/vial	8.8	PASS
CONTROL	29	33	nkat/vial	30.2	PASS
RESIDUAL MOISTURE	0	5	%	3	PASS

C. PLASMIN SOLVENT (654-078)					
APPEARANCE	Clear colorless Solution		--	PASS	PASS
pH	2.5	3.5	--	3.08	PASS

D. BUFFER (H00919)					
APPEARANCE	Clear colorless solution		--	PASS	PASS
pH	7.3	7.5	--	7.35	PASS

E. COAMATIC PLASMIN INHIBITOR KIT (823187)					
SLOPE	-0.0012	-0.0017	--	-0.00138	PASS
INTERCEPT	0.180	0.330	--	0.323	PASS
CORRELATION COEFFICIENT (r)	0.99	--	--	1.00	PASS
CONTROL RECOVERY					
Normal Control Plasma	74	104		91	PASS
Abnormal Control Plasma Lev.1	47	67		53	PASS
Abnormal Control Plasma Lev.2	25	45		29	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
S-2403	N0633349	2005-06	2 ml (x 1)
Plasmin	N0533018	2005-05	1 ml (x 1)
Plasmin Solvent	N0633387	2005-12	12.4 ml (x 1)
Buffer	N0633257	2005-06	10.8 ml (x 2)

PREPARED BY:

V MIVES

DATE: 6/17/2003

APPROVAL SIGNATURE:

J FACCIOLA

DATE: 6/17/2003