

CHROMOGENIX

PRODUCT:	COAMATIC PLASMIN INHIBITOR	PRODUCT # :	82318763
EXP. DATE:	2006-03	LOT # :	N0649635
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	8.1	PASS
FREE p - NITROANILINE	--	0.5	mol %	0.2	PASS
RESIDUAL MOISTURE	--	5.0	% H ₂ O	0.2	PASS

B. PLASMIN REAGENT (H00908)					
PLASMIN CONTENT	6.4	9.6	nkat/vial	8.0	PASS
CONTROL	29	33	nkat/vial	31.6	PASS
RESIDUAL MOISTURE	0	5	%	1.1	PASS

C. PLASMIN SOLVENT (654-078)					
APPEARANCE	Clear colorless Solution		--	PASS	PASS
pH	2.5	3.5	--	2.8	PASS

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

E. COAMATIC PLASMIN INHIBITOR KIT (823187)					
SLOPE	-0.0012	-0.0017	--	-0.0016	PASS
INTERCEPT	0.180	0.330	--	0.311	PASS
CORRELATION COEFFICIENT (r)	0.99	--	--	1.000	PASS
CONTROL RECOVERY					
Normal Control Plasma	74	104		89	PASS
Abnormal Control Plasma Lev.1	51	71		59	PASS
Abnormal Control Plasma Lev.2	25	45		33	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
S-2403	N0348182	2006-03	2 ml (x 1)
Plasmin	N0549085	2006-05	1 ml (x 1)
Plasmin Solvent	N0649632	2006-12	12.4 ml (x 1)
Buffer	N0649633	2006-06	10.8 ml (x 2)

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:

V. M. EVES

DATE: 6/21/2004

APPROVAL SIGNATURE:

J. FACCIOLA

DATE: 6/21/2004

Form QCM 82318763, Rev. 11/03