

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COAMATIC PLASMINOGEN	PRODUCT # : 82245263
EXP. DATE: 2005-11	LOT # : N0740266
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 822452/49730505

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
A. STREPTOKINASE/FIBRINOGEN (H00984)					
VISUAL INSPECTION	White lyoph. powder		--	PASS	PASS
RESIDUAL MOISTURE	0	5	% H ₂ O	0.36	PASS
B. S-2403,8.4 mg COAMATIC PLASMIN INHIBITOR (650591)					
SUBSTRATE CONCENTRATION	7.98	8.82	mg/vial	8.6	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.19	PASS
RESIDUAL MOISTURE	0	5	% H ₂ O	0.11	PASS

C. COAMATIC PLASMINOGEN KIT (822452)					
SLOPE	0.0024	0.0032	--	0.0030	PASS
INTERCEPT	0	0.025	--	0.013	PASS
STANDARD CURVE(r ²)	0.99	1.000	--	0.999	PASS
NORMAL CONTROL PLASMA	74	104	%	89	PASS
ABN. CONTROL PLASMA 1	46	66	%	52	PASS
ABN. CONTROL PLASMA 2	17	37	%	34	PASS

Kit Components:

NAME	LOT NUMBER	EXP. DATE	MFG. DATE
Streptokinase / Fibrinogen	N0549126	2005-11	7/28/2004
S-2403 8.4 mg	N0740168	2006-07	7/28/2004

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: *VINES* DATE: 7/28/2004

APPROVAL SIGNATURE: *J FACCIOLA* DATE: 7/28/2004