

**CERTIFICATE OF ANALYSIS**

# **CHROMOGENIX**

PRODUCT: <u>COAMATIC PLASMINOGEN</u>	PRODUCT # : <u>82245263</u>
EXP. DATE: <u>2006-02</u>	LOT # : <u>N0152655</u>
VENDOR: <u>INSTRUMENTATION LABORATORY</u>	ASSAYED PER QCM: <u>822452/49730505</u>

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
<b>A. STREPTOKINASE/FIBRINOGEN (H00984)</b>					
VISUAL INSPECTION	White lyoph. powder		--	PASS	PASS
RESIDUAL MOISTURE	0	5	% H <sub>2</sub> O	0.07	PASS
<b>B. S-2403,8.4 mg COAMATIC PLASMIN INHIBITOR (650591)</b>					
SUBSTRATE CONCENTRATION	7.98	8.82	mg/vial	8.56	PASS
FREE p-NITROANILINE	0	0.5	mol %	0	PASS
RESIDUAL MOISTURE	0	5	% H <sub>2</sub> O	0.60	PASS
<b>C. COAMATIC PLASMINOGEN KIT (822452)</b>					
SLOPE	0.0024	0.0032	--	0.00292	PASS
INTERCEPT	0	0.025	--	0.017	PASS
STANDARD CURVE(r <sup>2</sup> )	0.99	1.000	--	0.999	PASS
NORMAL CONTROL PLASMA	73	103	%	93	PASS
ABN. CONTROL PLASMA 1	43	63	%	60	PASS
ABN. CONTROL PLASMA 2	14	34	%	23	PASS

**Kit Components:**

NAME	LOT NUMBER	EXP. DATE	MFG. DATE
Streptokinase / Fibrinogen	N0840699	2006-02	2004-08
S-2403 8.4 mg	N1142241	2006-11	2004-11

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 BUES* DATE: 12/22/2004

APPROVAL SIGNATURE: *J FACCIOLA* DATE: 12/22/2004