

**CERTIFICATE OF ANALYSIS**

# **CHROMOGENIX**

PRODUCT: <u>COAMATIC PLASMINOGEN</u>	PRODUCT # : <u>82245263</u>
EXP. DATE: <u>2005-05</u>	LOT # : <u>N1236386</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	0.1	PASS

<b>B. S-2403,8.4 mg COAMATIC PLASMIN INHIBITOR (650591)</b>					
SUBSTRATE CONCENTRATION	7.98	8.82	mg/vial	8.32	PASS
FREE p-NITROANILINE	0	0.5	mol %	0.02	PASS
RESIDUAL MOISTURE	0	5	% H <sub>2</sub> O	0.5	PASS

<b>C. COAMATIC PLASMINOGEN KIT (822452)</b>					
SLOPE	0.0024	0.0032	--	0.0031	PASS
INTERCEPT	0	0.025	--	0.012	PASS
STANDARD CURVE(r <sup>2</sup> )	0.99	1.000	--	1.000	PASS
NORMAL CONTROL PLASMA	70	100	%	86	PASS
ABN. CONTROL PLASMA 1	43	63	%	53	PASS
ABN. CONTROL PLASMA 2	18	38	%	29	PASS

**Kit Components:**

NAME	LOT NUMBER	EXP. DATE	MFG. DATE
Streptokinase / Fibrinogen	N1136046	2005-05	2003-11
S-2403 8.4 mg	N1135779	2005-11	2003-11

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: Donna Tencza DATE: 12/29/03

APPROVAL SIGNATURE: M. Brunswick DATE: 12/29/03