CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	CONTROL PLASMA ABNORMAL LEVEL 1 & 2	PRODUCT # :	82355963
EXP. DATE:	2005-09	LOT # :	N1236489
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823559

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	PASS/FAIL
	MIN	MAX	UNITS		
Clarity (A_{405}) Level 1	--	0.400	--	0.216	PASS
Clarity (A_{405}) Level 2	--	0.400	--	0.123	PASS
Antithrombin Activity					
Level 1	50	60	%	55	PASS
Level 2	20	30	%	29	PASS
Plasmin Inhibitor Activity					
Level 1	45	65	%	64	PASS
Level 2	20	40	%	34	PASS
Plasminogen Activity					
Level 1	40	60	%	56	PASS
Level 2	15	30	%	29	PASS
Protein C Activity					
Level 1	run and report		%	53	N/A
Level 2	run and report		%	25	N/A
Factor VIII Activity					
Level 1	run and report		%	73	N/A
Level 2	run and report		%	34	N/A

Kit Components:

Name	Lot Number	Exp. date	Volume
Abnormal Level 1	N0934345	2005-09	0.5 ml
Abnormal Level 2	N0934346	2005-09	0.5 ml

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: *D. Tencza* DATE: 01/29/04

APPROVAL SIGNATURE: *J. Facciola* DATE: 01/29/04

Form QCM 823559, Rev. 12/03