

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	Factor V Deficient Plasma	PRODUCT # :	82314663
EXP. DATE:	2005-10	LOT # :	N0448590
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	H01450

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	DISPOSITION
	MIN	MAX			
APC ratio on ACL					
<i>(1 part Control Plasma Level 1 + 4 parts V-Def plasma)</i>					
APT Time	--	38	seconds	36	PASS
APC Ratio	2.3	3.0	--	2.9	PASS
<i>(1 part heterozygous plasma @ 1IU Heparin/ml + 4 parts V-Def plasma)</i>					
APT Time	--	38	seconds	38	PASS
APC Ratio	1.4	1.9		1.9	PASS
<i>(1 part homozygous plasma + 4 parts V-Def plasma)</i>					
APT Time	--	38	seconds	37	PASS
APC Ratio	--	1.4		1.4	PASS
Factor V Content (on ST-4)					
Factor V Content	--	4.5	%	0.7	PASS
Residual Moisture					
H ₂ O Content	--	5	%	1.2	PASS

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
Factor V Deficient Plasma	N0448590	2005-10	4 ml (x 5)

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. Teneza DATE: 09/27/04

APPROVAL SIGNATURE: J. Facciola DATE: 09/27/04