

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

PRODUCT:	Factor V Deficient Plasma	PRODUCT #:	82314663
EXP. DATE:	2006-01	LOT #:	N0740150
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	H01450

TEST DESCRIPTION	SPECIFICATIONS		RESULTS	DISPOSITION	
APC ratio on ACL	MIN	MAX	UNITS	PASS/FAIL	
<b>(1 part Control Plasma Level 1 + 4 parts V-Def plasma)</b>					
APT Time	--	38	seconds	32	PASS
APC Ratio	2.5	3.2	--	2.8	PASS
<b>(1 Part Control Plasma Level 2 + 4 parts V-Def plasma)</b>					
APT Time	27	40	seconds	33	PASS
APC Ratio	1.4	1.9	--	1.75	PASS
<b>(1 part Control Plasma Level 2 @ 1IU/mL Heparin + 4 parts V-Def plasma)</b>					
APC Ratio	--	1.85		1.68	PASS
<b>(1 part homozygous plasma + 4 parts V-Def plasma)</b>					
APT Time	--	38	seconds	34	PASS
APC Ratio	--	1.4		1.3	PASS
<b>Factor V Content (on ST-4)</b>					
Factor V Content	--	4.5	%	0.4	PASS
<b>Residual Moisture</b>					
H <sub>2</sub> O Content	--	5	%	0.98	PASS

**Test Reagent Information (Not included in Kit):**

DESCRIPTION	LOT NUMBER	EXP. DATE
APC/CaCl <sub>2</sub>	N0649802	2005-12
APTT Reagent	N0649599	2005-12
CaCl <sub>2</sub>	N0448773	2007-04
Control Plasma Level 1	N0347918	2006-03
Control Plasma Level 2	N1236589	2005-06

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: 09/27/04

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