

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V	PRODUCT #:	82312063
EXP. DATE:	2015-02	LOT #:	N0936260
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823120

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL	28	46	seconds	32	PASS
Diluted Control Plasma Level 1					
Diluted Control Plasma Level 2	29	49	seconds	32	PASS

APC-V ratio on ACL					
Control Plasma Level 1	2.8	3.2	--	2.9	PASS
Control Plasma Level 2	1.4	1.9	--	1.5	PASS

Kit Components

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl ₂	N0132840	2016-01	8 ml (x 1)
APTT Reagent	N0835863	2015-02	16 ml (x 1)
APC/CaCl ₂	N0936257	2015-03	2 ml (x 4)
Control Plasma Level 1	N0936259	2015-02	1 ml (x 1)
Control Plasma Level 2	N0635141	2015-06	1 ml (x 1)
V-DEF Plasma	N0735574	2016-09	4 ml (x 4)

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: N. Patel N. Patel DATE: 9-25-13
9/25/2013

APPROVAL SIGNATURE: D. Tenega D. Tenega DATE: 9/25/2013 9/25/13
9/25/2013