

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V	PRODUCT #:	82312063
EXP. DATE:	2017-02	LOT #:	N1058939
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823120

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
Diluted Control Plasma Level 1	29	47	seconds	33	PASS
Diluted Control Plasma Level 2	33	53	seconds	34	PASS

APC-V ratio on ACL					
Control Plasma Level 1	2.8	3.2	--	2.8	PASS
Control Plasma Level 2	1.4	1.9	--	1.8	PASS

Kit Components

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl ₂	N0958330	2018-09	8 ml (x 1)
APTT Reagent	N0858135	2017-02	16 ml (x 1)
APC/CaCl ₂	N0958713	2017-03	2 ml (x 4)
Control Plasma Level 1	N1058936	2017-02	1 ml (x 1)
Control Plasma Level 2	N0958427	2017-09	1 ml (x 1)
V-DEF Plasma	N0958581	2018-11	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. M. Patel

DATE: 10/21/2015 10/21/15

APPROVAL SIGNATURE: D. Teneza P. Anza

DATE: 10/21/2015 10/21/15