

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V	PRODUCT #:	82312063
EXP. DATE:	2016-08	LOT #:	N0254981
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	34	Pass
Diluted Control Plasma Level 2	28	48	seconds	36	Pass

APC-V ratio on ACL					
Control Plasma Level 1	2.8	3.2	--	3.1	Pass
Control Plasma Level 2	1.4	1.9	--	1.8	Pass

Kit Components

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl ₂	N0154300	2018-01	8 ml (x 1)
APTT Reagent	N0254684	2016-08	16 ml (x 1)
APC/CaCl ₂	N0254974	2016-08	2 ml (x 4)
Control Plasma Level 1	N0254980	2016-08	1 ml (x 1)
Control Plasma Level 2	N0154142	2017-01	1 ml (x 1)
V-DEF Plasma	N0154299	2018-03	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 98/78/EC Directive according to which they are CE marked.

PREPARED BY: N. Patel N.M. Patel

DATE: 3/24/2015 3-24-15

APPROVAL SIGNATURE: D. Tencza D. Anza

DATE: 3/24/2015 3/25/15