

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V-S	PRODUCT # :	82313863
EXP. DATE:	2018-11	LOT # :	N0670601
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823138

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
Diluted Control Plasma Level 1	28	45	seconds	33	PASS
Diluted Control Plasma Level 2	30	50	seconds	35	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	N0663508	2019-06	2 ml (x 2)
APTT Reagent	N0579958	2018-11	4 ml (x 2)
APC/CaCl ₂	N0670293	2018-12	2 ml (x 2)
Control Plasma Level 1	N0670546	2018-11	1 ml (x 1)
Control Plasma Level 2	N0579954	2019-05	1 ml (x 1)
V-DEF Plasma	N0177393	2020-03	4 ml (x 2)

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: 6/29/2017 6.29.17

APPROVAL SIGNATURE: D. Tencza P. Amza

DATE: 6/29/2017 6/29/17