

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V-S	PRODUCT #:	82313863
EXP. DATE:	2017-03	LOT #:	N1159330
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	31	46	seconds	32	PASS
Diluted Control Plasma Level 2	33	53	seconds	33	PASS

APC-V ratio on ACL	MIN	MAX	UNITS	RESULTS	Pass/Fail
Control Plasma Level 1	2.8	3.2	--	3.0	PASS
Control Plasma Level 2	1.4	1.9	--	1.8	PASS

Kit Components:

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl ₂	N0958328	2018-09	2 ml (x 2)
APTT Reagent	N0958429	2017-03	4 ml (x 2)
APC/CaCl ₂	N1059106	2017-04	2 ml (x 2)
Control Plasma Level 1	N1159329	2017-03	1 ml (x 1)
Control Plasma Level 2	N0958427	2017-09	1 ml (x 1)
V-DEF Plasma	N1058955	2018-12	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: 11/11/2015 11/11/15

APPROVAL SIGNATURE: D. Tenza D. Tenza

DATE: 11/11/2015 11/11/15