

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V-S	PRODUCT # :	82313863
EXP. DATE:	2015-10	LOT # :	N0640607
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	30	47	seconds	32	PASS
Diluted Control Plasma Level 2	26	46	seconds	34	PASS

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

Kit Components:

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl ₂	N0349521	2017-03	2 ml (x 2)
APTT Reagent	N0449913	2015-10	4 ml (x 2)
APC/CaCl ₂	N0640606	2015-12	2 ml (x 2)
Control Plasma Level 1	N0540505	2015-10	1 ml (x 1)
Control Plasma Level 2	N0540174	2016-05	1 ml (x 1)
V-DEF Plasma	N0835781	2016-10	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. M. Patel

DATE: 6.20.14

APPROVAL SIGNATURE: D. Anzola

DATE: 6-20-14