

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V-S	PRODUCT #:	82313863
EXP. DATE:	2016-06	LOT #:	N0254641
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	29	47	seconds	36	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	N1143457	2017-11	2 ml (x 2)
APTT Reagent	N1243567	2016-06	4 ml (x 2)
APC/CaCl ₂	N0154436	2016-07	2 ml (x 2)
Control Plasma Level 1	N0154416	2016-06	1 ml (x 1)
Control Plasma Level 2	N0154142	2017-01	1 ml (x 1)
V-DEF Plasma	N0148152	2017-03	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: 2-19-15
 APPROVAL SIGNATURE: D. Teneza D. Teneza DATE: 2/19/15