

**CERTIFICATE OF ANALYSIS**

***CHROMOGENIX***

PRODUCT:	COATEST APC Resistance V-S	PRODUCT #:	82313863
EXP. DATE:	2018-04	LOT #:	N1166224
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823138

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	Pass/Fail
	MIN	MAX	UNITS		
APT-time on ACL					
Diluted Control Plasma Level 1	29	45	seconds	32	PASS
Diluted Control Plasma Level 2	30	50	seconds	34	PASS

APC-V ratio on ACL					
Control Plasma Level 1	2.8	3.2	--	2.9	PASS
Control Plasma Level 2	1.4	1.9	--	1.7	PASS

**Kit Components:**

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl <sub>2</sub>	N1065654	2019-10	2 ml (x 2)
APTT Reagent	N1065788	2018-04	4 ml (x 2)
APC/CaCl <sub>2</sub>	N1166219	2018-05	2 ml (x 2)
Control Plasma Level 1	N1166222	2018-04	1 ml (x 1)
Control Plasma Level 2	N1065787	2018-10	1 ml (x 1)
V-DEF Plasma	N1065653	2019-12	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: M. Oettinger M. Oettinger      DATE: 11/23/2016 11-23-16

APPROVAL SIGNATURE: N. Patel n.m. Patel      DATE: 11/23/2016 11-23-16