

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

PRODUCT:	COATEST APC Resistance V	PRODUCT #:	82312063
EXP. DATE:	2018-10	LOT #:	N0579951
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823120

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
<b>APT-time on ACL</b>					
Diluted Control Plasma Level 1	28	45	seconds	33	PASS
Diluted Control Plasma Level 2	29	49	seconds	36	PASS

<b>APC-V ratio on ACL</b>					
Control Plasma Level 1	2.8	3.2	--	3.0	PASS
Control Plasma Level 2	1.4	1.9	--	1.7	PASS

**Kit Components**

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl <sub>2</sub>	N1266757	2019-12	8 ml (x 1)
APTT Reagent	N0479177	2018-10	16 ml (x 1)
APC/CaCl <sub>2</sub>	N0579782	2018-11	2 ml (x 4)
Control Plasma Level 1	N0579974	2018-10	1 ml (x 1)
Control Plasma Level 2	N0177087	2019-01	1 ml (x 1)
V-DEF Plasma	N0479178	2020-06	4 ml (x 4)

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: 5/19/2017 *5-19-17*

APPROVAL SIGNATURE: D. Tencza *D. Tencza*      DATE: 5/19/2017 *5/19/17*