

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V	PRODUCT #:	82312063
EXP. DATE:	2018-07	LOT #:	N0177320
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823120

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
Diluted Control Plasma Level 1	29	45	seconds	33	PASS
Diluted Control Plasma Level 2	29	49	seconds	34	PASS

APC-V ratio on ACL					
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	N1266757	2019-12	8 ml (x 1)
APTT Reagent	N0177160	2018-07	16 ml (x 1)
APC/CaCl ₂	N0177291	2018-07	2 ml (x 4)
Control Plasma Level 1	N0177319	2018-07	1 ml (x 1)
Control Plasma Level 2	N0177087	2019-01	1 ml (x 1)
V-DEF Plasma	N0177393	2020-03	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: 2/13/2017 *2-13-17*

APPROVAL SIGNATURE: D. Tencza *D. Tencza* DATE: 2/13/2017 *2/13/17*