

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance V	PRODUCT #:	82312063
EXP. DATE:	2018-01	LOT # :	N0864700
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823120

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
Diluted Control Plasma Level 1	29	45	seconds	34	PASS
Diluted Control Plasma Level 2	30	50	seconds	35	PASS

APC-V ratio on ACL	MIN	MAX	UNITS	RESULTS	Pass/Fail
Control Plasma Level 1	2.8	3.2	--	2.8	PASS
Control Plasma Level 2	1.4	1.9	--	1.7	PASS

Kit Components

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl ₂	N0763872	2019-07	8 ml (x 1)
APTT Reagent	N0764113	2018-01	16 ml (x 1)
APC/CaCl ₂	N0864378	2018-02	2 ml (x 4)
Control Plasma Level 1	N0864699	2018-01	1 ml (x 1)
Control Plasma Level 2	N0160379	2018-01	1 ml (x 1)
V-DEF Plasma	N0764112	2019-09	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 DATE: Aug.24, 2016

APPROVAL SIGNATURE: D. Tencza DATE: Aug.24, 2016