

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: <u>COATEST APC Resistance Kit</u>	PRODUCT # : <u>82264363</u>
EXP. DATE: <u>2018-10</u>	LOT # : <u>N0771279</u>
VENDOR: <u>INSTRUMENTATION LABORATORY</u>	ASSAYED PER QCM: <u>822643</u>

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APC-ratio on ACL					
Control Plasma Level 1 (Lot: <u>N1043066</u>)	3.5	4.4	--	3.7	PASS
Control Plasma Level 2 (Lot: <u>N0958710</u>)	--	2.3	--	1.8	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
CaCl ₂	N1266757	2019-12	8 ml (x 1)
APTT Reagent	N0479177	2018-10	16 ml (x 1)
APC/CaCl ₂	N0579642	2018-11	2 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: 8/3/2017 *8.3-17*

APPROVAL SIGNATURE: *D. Tencza* *D. Tencza*

DATE: 8/3/2017 *8/3/17*