

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: COATEST APC Resistance Kit	PRODUCT #: 82264363
EXP. DATE: 2018-01	LOT #: N0864701
VENDOR: INSTRUMENTATION LABORATORY	ASSAYED PER QCM: 822643

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

Kit Components:

Name	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	N0864377	2018-02	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: Aug. 24, 2016 *Aug 24, 2016*

APPROVAL SIGNATURE: D. Tencza *D. Tencza*

DATE: Aug. 24, 2016 *Aug. 24, 2016*