

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance Kit	PRODUCT #:	82264363
EXP. DATE:	2019-07	LOT #:	N0185250
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	822643

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APC-ratio on ACL					
Control Plasma Level 1 (Lot: N0864887)	3.5	4.4	--	4.0	PASS
Control Plasma Level 2 (Lot: N0462226)	--	2.3	--	2.1	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
CaCl ₂	N0184985	2021-01	8 ml (x 1)
APTT Reagent	N0185247	2019-07	16 ml (x 1)
APC/CaCl ₂	N0185249	2019-07	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: 2/23/2018 *2-23-18*

APPROVAL SIGNATURE: D. Tencza *D Tencza*

DATE: 2/23/2018 *2/23/18*