

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT: <u>COATEST APC Resistance Kit</u>	PRODUCT #: <u>82264363</u>
EXP. DATE: <u>2015-07</u>	LOT #: <u>N0248889</u>
VENDOR: <u>INSTRUMENTATION LABORATORY</u>	ASSAYED PER QCM: <u>822643</u>

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
<u>APC-ratio on ACL</u>					
Control Plasma Level 1 (Lot: <u>N1021838</u>)	3.5	4.4	--	4.1	PASS
Control Plasma Level 2 (Lot: <u>N0921586</u>)	--	2.3	--	2.0	PASS

Kit Components:

Name	Lot Number	Exp. date	Volume
CaCl ₂	N0132840	2016-01	8 ml (x 1)
APTT Reagent	N0148544	2015-07	16 ml (x 1)
APC/CaCl ₂	N0248768	2015-08	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:

N. Patel *N. Patel*

DATE:

3-10-14

3/4/2014

APPROVAL SIGNATURE:

D. Teneza *D. Teneza*

DATE:

3/10/14

3/4/2014