

CERTIFICATE OF ANALYSIS

CHROMOGENIX

PRODUCT:	COATEST APC Resistance Kit	PRODUCT # :	82264363
EXP. DATE:	2016-08	LOT # :	N0757491
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: N1237730)	3.5	4.4	--	4.0	Pass
Control Plasma Level 2 (Lot: N0741081)	--	2.3	--	2.0	Pass

Kit Components:

Name	Lot Number	Exp. date	Volume
CaCl ₂	N0154300	2018-01	8 ml (x 1)
APTT Reagent	N0254684	2016-08	16 ml (x 1)
APC/CaCl ₂	N0757490	2017-01	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 P.M. Patel

DATE: 7-29-15
7/29/2015

APPROVAL SIGNATURE: D. Tencza J. Tencza

DATE: 7/29/2015
7/29/2015