

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

PRODUCT:	COATEST APC Resistance V	PRODUCT #:	82312063
EXP. DATE:	2016-01	LOT #:	N0942223
VENDOR:	INSTRUMENTATION LABORATORY	ASSAYED PER QCM:	823120

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL	30	47	seconds	34	PASS
Diluted Control Plasma Level 1					
Diluted Control Plasma Level 2	26	46	seconds	35	PASS

APC-V ratio on ACL					
TEST DESCRIPTION	MIN	MAX	UNITS	RESULTS	Pass/Fail
Control Plasma Level 1	2.8	3.2	--	2.8	PASS
Control Plasma Level 2	1.4	1.9	--	1.7	PASS

**Kit Components**

DESCRIPTION	LOT NUMBER	EXP. DATE	VOLUME
CaCl <sub>2</sub>	N0741332	2017-07	8 ml (x 1)
APTT Reagent	N0741426	2016-01	16 ml (x 1)
APC/CaCl <sub>2</sub>	N0841956	2016-02	2 ml (x 4)
Control Plasma Level 1	N0842116	2016-01	1 ml (x 1)
Control Plasma Level 2	N0540174	2016-05	1 ml (x 1)
V-DEF Plasma	N0741571	2017-09	4 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.M. Patel

DATE: 9/19/2014 9-19-14

APPROVAL SIGNATURE: D. Tenca J. Tenca

DATE: 9/19/2014 9/19/14