

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**



PRODUCT NAME:	COATEST APC Resistance V	EXPIRATION DATE:	2022-04
PRODUCT NUMBER:	82312063		
LOT NUMBER:	N1209104		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
<b>APT-time on ACL</b>					
Diluted Control Plasma Level 1	28	47	seconds	31	PASS
Diluted Control Plasma Level 2	29	49	seconds	32	PASS

<b>APC-V ratio on ACL</b>					
Control Plasma Level 1	2.8	3.2	--	3.1	PASS
Control Plasma Level 2	1.4	1.9	--	1.8	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N1008097	8 mL
COATEST APC Resistance APTT reagent	N1007953	16 mL
COATEST APC Resistance APC/CaCl2	N1209102	2 mL
COATEST APC Resistance Control Plasma Level 1	N1209103	1 mL
COATEST APC Resistance Control Plasma Level 2	N0907239	1 mL
COATEST APC Resistance V-DEF Plasma	N1008100	4 mL

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: Nehal Patel *N.M. Patel* DATE: 1-13-21  
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TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz* DATE: 1-13-21  
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TITLE: Technical Supervisor