

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

**Instrumentation  
Laboratory**  
A Werfen Company

PRODUCT NAME:	COATEST APC Resistance V	EXPIRATION DATE:	2020-10
PRODUCT NUMBER:	82312063		
LOT NUMBER:	N0696303		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
Diluted Control Plasma Level 1	30	47	seconds	34	PASS
Diluted Control Plasma Level 2	31	51	seconds	34	PASS

APC-V ratio on ACL					
Control Plasma Level 1	2.8	3.2	--	3.1	PASS
Control Plasma Level 2	1.4	1.9	--	1.9	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl <sub>2</sub>	N0495325	8 mL
COATEST APC Resistance APTT reagent	N0495328	16 mL
COATEST APC Resistance APC/CaCl <sub>2</sub>	N0696301	2 mL
COATEST APC Resistance Control Plasma Level 1	N0696302	1 mL
COATEST APC Resistance Control Plasma Level 2	N0596176	1 mL
COATEST APC Resistance V-DEF Plasma	N0596037	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: 6/27/2019  
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TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz* DATE: 6/27/2019  
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TITLE: Technical Supervisor