

# CERTIFICATE OF ANALYSIS

**CHROMOGENIX**


**Instrumentation  
Laboratory**  
A Werfen Company

PRODUCT NAME:	COATEST APC Resistance V-S	EXPIRATION DATE: 2022-02
PRODUCT NUMBER:	82313863	
LOT:	N0907151	

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	Pass/Fail
	MIN	MAX	UNITS		
APT-time on ACL Diluted Control Plasma Level 1	28	42	seconds	29	Pass
Diluted Control Plasma Level 2	28	48	seconds	31	Pass

APC-V ratio on ACL	MIN	MAX	UNITS	RESULTS	Pass/Fail
Control Plasma Level 1	2.8	3.2	--	2.9	Pass
Control Plasma Level 2	1.4	1.9	--	1.7	Pass

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl <sub>2</sub>	N0906945	2 mL
COATEST APC Resistance APTT reagent	N0806734	4 mL
COATEST APC Resistance APC/CaCl <sub>2</sub>	N0907101	2 mL
COATEST APC Resistance Control Plasma Level 1	N0907115	1 mL
COATEST APC Resistance Control Plasma Level 2	N0303159	1 mL
COATEST APC Resistance V-DEF Plasma	N0404073	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:

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SIGNATURE

DATE:

09/29/2020.

TITLE: QC Analyst I

APPROVAL SIGNATURE:

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DATE:

9/28/20

TITLE: Senior QC Analyst