

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

**Instrumentation  
Laboratory**  
A Werfen Company

PRODUCT NAME:	COATEST APC Resistance Control Plasma Level 1	EXPIRATION DATE:	2021-12
PRODUCT NUMBER:	82265063		
LOT	N1190184		

TEST DESCRIPTION	SPECIFICATIONS		RESULTS	DISPOSITION
Analysis with COATEST APC R:	MIN	MAX	UNITS	PASS/FAIL
APT Time <u>CaCl<sub>2</sub></u>	28	34	seconds	PASS
<u>APC/CaCl<sub>2</sub></u>	90	--	seconds	PASS
APC Ratio	3.5	4.4	--	PASS

Analysis with COATEST APC R V:	MIN	MAX	UNITS	RESULTS	DISPOSITION
APT Time <u>CaCl<sub>2</sub></u>	--	38	seconds	37	PASS
<u>APC/CaCl<sub>2</sub></u>	75	--	seconds	115	PASS
APC Ratio	2.7	3.2	--	3.1	PASS

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: 12/17/2019 *12-17-19*  
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TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz* DATE: 12/17/2019 *12/17/19*  
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TITLE: Technical Supervisor