

CERTIFICATE OF ANALYSIS

CHROMOGENIX **werfen**

PRODUCT NAME:	COATEST APC Resistance V-S	EXPIRATION DATE: 2026-07-31
PRODUCT NUMBER:	00082313863	
LOT:	N0259992	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
APT-time on ACL	MIN	MAX			
Diluted Control Plasma Level 1	27	44	seconds	33	PASS
Diluted Control Plasma Level 2	31	51	seconds	37	PASS

APC-V ratio on ACL	MIN	MAX	UNITS	RESULTS	Pass/Fail
Control Plasma Level 1	2.8	3.2	--	3.0	PASS
Control Plasma Level 2	1.4	1.9	--	1.6	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl ₂	N0259778	2 mL
COATEST APC Resistance APTT reagent	N0259777	4 mL
COATEST APC Resistance APC/CaCl ₂	N0259984	2 mL
COATEST APC Resistance Control Plasma Level 1	N0259985	1 mL
COATEST APC Resistance Control Plasma Level 2	N0159585	1 mL
COATEST APC Resistance V-DEF Plasma	N0350657	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.

PREPARED BY:

Brianna Randazzo
PRINT

SIGNATURE

DATE:

4/11/2025
4/11/2025

TITLE: QC Analyst II

APPROVAL SIGNATURE:

Nehal Patel

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SIGNATURE

DATE:

4-11-25
4/11/2025

TITLE: Senior Group Leader