

# CERTIFICATE OF ANALYSIS

**CHROMOGENIX** **werfen**

PRODUCT NAME:	COATEST APC Resistance V	EXPIRATION DATE:	2026-09-30
PRODUCT NUMBER:	00082312063		
LOT NUMBER:	N0351161		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
APT-time on ACL	MIN	MAX			
Diluted Control Plasma Level 1	28	44	seconds	32	PASS
Diluted Control Plasma Level 2	30	50	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 CaCl2	N0350849	8 mL
COATEST APC Resistance APTT reagent	N0350844	16 mL
COATEST APC Resistance APC/CaCl2	N0351157	2 mL
COATEST APC Resistance Control Plasma Level 1	N0351160	1 mL
COATEST APC Resistance Control Plasma Level 2	N0250218	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: Monika Skowronska  
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Monika Skowronska  
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DATE: 4/17/2025

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel  
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DATE: 4-17-25  
4/17/2025

TITLE: Senior Group Leader