

CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

PRODUCT NAME:	COATEST APC Resistance V-S	EXPIRATION DATE:	2026-07-31
PRODUCT NUMBER:	00082313663		
LOT:	N0259992		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
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					
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 CaCl2	N0259778	2 mL
COATEST APC Resistance APTT reagent	N0259777	4 mL
COATEST APC Resistance APC/CaCl2	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 *Brianna Randazzo*
 PRINT SIGNATURE

DATE: 4/11/2025
 4/11/2025

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.m. Patel*
 PRINT SIGNATURE

DATE: 4-11-25
 4/11/2025

TITLE: Senior Group Leader