

CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

PRODUCT NAME:	COATEST APC Resistance V	EXPIRATION DATE:	2027-04-30
PRODUCT NUMBER:	00082312063		
LOT NUMBER:	N1158524		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
Diluted Control Plasma Level 1	27	43	seconds	35	PASS
Diluted Control Plasma Level 2	28	48	seconds	36	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	N1057318	8 mL
COATEST APC Resistance APTT reagent	N1057330	16 mL
COATEST APC Resistance APC/CaCl2	N1158522	2 mL
COATEST APC Resistance Control Plasma Level 1	N1158523	1 mL
COATEST APC Resistance Control Plasma Level 2	N1057583	1 mL
COATEST APC Resistance V-DEF Plasma	N1057140	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 *Monika Skowronska* DATE: 12-17-25
 PRINT SIGNATURE 12/17/2025

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *p.m. Patel* DATE: 12-17-25
 PRINT SIGNATURE 12/17/2025

TITLE: Senior Group Leader