

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**


**Instrumentation  
Laboratory**  
 A Werfen Company

PRODUCT NAME:	COATEST APC Resistance V	EXPIRATION DATE:	2026-01-31
PRODUCT NUMBER:	00082312063		
LOT NUMBER:	N0844861		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
Diluted Control Plasma Level 1	27	44	seconds	34	PASS
Diluted Control Plasma Level 2	31	51	seconds	38	PASS

APC-V ratio on ACL					
	MIN	MAX	UNITS	RESULTS	Pass/Fail
Control Plasma Level 1	2.8	3.2	--	3.1	PASS
Control Plasma Level 2	1.4	1.9	--	1.7	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N0744320	8 mL
COATEST APC Resistance APTT reagent	N0744434	16 mL
COATEST APC Resistance APC/CaCl2	N0844859	2 mL
COATEST APC Resistance Control Plasma Level 1	N0844860	1 mL
COATEST APC Resistance Control Plasma Level 2	N0744667	1 mL
COATEST APC Resistance V-DEF Plasma	N0744321	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;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: Monika Skowronska *Monika Skowronska* DATE: 8/30/2024 *8-30-24*  
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.M. Patel* DATE: 8/30/2024 *8-30-24*  
 PRINT SIGNATURE

TITLE: Senior Group Leader