

**CERTIFICATE OF ANALYSIS**

**CHROMOGENIX**

**Instrumentation  
Laboratory**

A Werfen Company

PRODUCT NAME	COATEST APC Resistance V-S	EXPIRATION DATE	2023-09
PRODUCT NUMBER	82313863		
LOT	N0421453		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
Diluted Control Plasma Level 1	25	42	seconds	32	PASS
Diluted Control Plasma Level 2	25	45	seconds	33	PASS

APC-V ratio on ACL					
Control Plasma Level 1	2.8	3.2	--	2.9	PASS
Control Plasma Level 2	1.4	1.9	--	1.8	PASS

**KIT COMPONENTS:**

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl <sub>2</sub>	N0320644	2 mL
COATEST APC Resistance APTT reagent	N0320646	4 mL
COATEST APC Resistance APC/CaCl <sub>2</sub>	N0321020	2 mL
COATEST APC Resistance Control Plasma Level 1	N0421452	1 mL
COATEST APC Resistance Control Plasma Level 2	N0320802	1 mL
COATEST APC Resistance V-DEF Plasma	N0320645	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

*H Patel* *N in Patel*  
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DATE 4-15-22  
4/15/2022

TITLE: Senior QC Analyst

APPROVAL SIGNATURE:

*D. Tenzga* *D. Tenzga*  
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DATE 4/15/22  
4/15/2022

TITLE: Senior Group Leader

QCM00823138-1. Rev. 01