

CERTIFICATE OF ANALYSIS

CHROMOGENIX

**Instrumentation
Laboratory**
A Werfen Company

PRODUCT NAME:	COATEST APC Resistance V-S	EXPIRATION DATE:	2022-07
PRODUCT NUMBER:	82313863		
LOT:	N0119990		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APC-time on ACL					
Diluted Control Plasma Level 1	28	47	seconds	30	Pass
Diluted Control Plasma Level 2	29	49	seconds	32	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	--	1.8	Pass

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N0119871	2 mL
COATEST APC Resistance APTT reagent	N0119865	4 mL
COATEST APC Resistance APC/CaCl2	N0119988	2 mL
COATEST APC Resistance Control Plasma Level 1	N0119989	1 mL
COATEST APC Resistance Control Plasma Level 2	N0907239	1 mL
COATEST APC Resistance V-DEF Plasma	N0404073	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: D. Teneza *D. Teneza*
PRINT SIGNATURE

DATE: 2/9/21
2/9/2021

TITLE: Senior QC Analyst

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

DATE: 2-9-21
2/9/2021

TITLE: Senior QC Analyst