

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME:	COATEST APC Resistance V	EXPIRATION DATE:	2021-10
PRODUCT NUMBER:	82312063		
LOT NUMBER:	N0504528		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
Diluted Control Plasma Level 1	28	47	seconds	31	PASS
Diluted Control Plasma Level 2	28	48	seconds	32	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	N0403789	8 mL
COATEST APC Resistance APTT reagent	N0403542	16 mL
COATEST APC Resistance APC/CaCl2	N0403944	2 mL
COATEST APC Resistance Control Plasma Level 1	N0504527	1 mL
COATEST APC Resistance Control Plasma Level 2	N0303159	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: Nehal Patel *N. M. Patel* DATE: 5-27-20
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TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz* DATE: 5-27-20
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TITLE: Technical Supervisor