

CERTIFICATE OF ANALYSIS

CHROMOGENIX

**Instrumentation
Laboratory**

A Werfen Company

PRODUCT NAME:	COATEST APC Resistance V-S	EXPIRATION DATE: 2021-01
PRODUCT NUMBER:	82313863	
LOT:	N0797379	

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
Diluted Control Plasma Level 1	29	46	seconds	34	PASS
Diluted Control Plasma Level 2	31	51	seconds	35	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	--	1.7	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N0696829	2 mL
COATEST APC Resistance APTT reagent	N0796923	4 mL
COATEST APC Resistance APC/CaCl2	N0797061	2 mL
COATEST APC Resistance Control Plasma Level 1	N0797375	1 mL
COATEST APC Resistance Control Plasma Level 2	N0596176	1 mL
COATEST APC Resistance V-DEF Plasma	N0797374	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*
PRINT SIGNATURE

DATE: 8/8/2019 *8-8-19*

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz*
PRINT SIGNATURE

DATE: 8/8/2019 *8/8/19*

TITLE: Technical Supervisor