

CERTIFICATE OF ANALYSIS




**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME:	COATEST APC Resistance V	EXPIRATION DATE:	2023-06
PRODUCT NUMBER:	82312063		
LOT NUMBER:	N0129156		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APT-time on ACL					
Diluted Control Plasma Level 1	24	42	seconds	28	PASS
Diluted Control Plasma Level 2	25	45	seconds	30	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 CaCl2	N1118204	8 mL
COATEST APC Resistance APTT reagent	N1218570	16 mL
COATEST APC Resistance APC/CaCl2	N0128927	2 mL
COATEST APC Resistance Control Plasma Level 1	N0129155	1 mL
COATEST APC Resistance Control Plasma Level 2	N1218391	1 mL
COATEST APC Resistance V-DEF Plasma	N1218392	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: Bhumi Vasoya *Bhumi Vasoya* DATE: 1/28/2022 *01/28/22*
 PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Donna Tencza *Donna Tencza* DATE: 1/28/2022 *1/28/22*
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TITLE: Senior Group Leader