

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME:	COATEST APC Resistance Kit	EXPIRATION DATE:	2020-10
PRODUCT NUMBER:	82264363		
LOT NUMBER :	N0595847		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APC-ratio on ACL					
Control Plasma Level 1 (Lot: __N0193318____)	3.5	4.4	--	3.9	PASS
Control Plasma Level 2 (Lot: __N0394767____)	--	2.3	--	1.9	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N0495325	8 mL
COATEST APC Resistance APTT reagent	N0495328	16 mL
COATEST APC Resistance APC/CaCl2	N0595846	2 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.

6-5-19

PREPARED BY: Nehal Patel *N-m. Patel*
 PRINT SIGNATURE

DATE: 6/5/2019

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz*
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DATE: 6-5-19
 6/5/2019

TITLE: Technical Supervisor