

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

PRODUCT NAME:	COATEST APC Resistance Kit	EXPIRATION DATE:	2021-07
PRODUCT NUMBER:	82264363		
LOT NUMBER:	N0201766		

TEST DESCRIPTION	SPECIFICATIONS			RESULTS	Pass/Fail
	MIN	MAX	UNITS		
APC-ratio on ACL					
Control Plasma Level 1 (Lot: ____ N0193318)	3.5	4.4	--	3.8	PASS
Control Plasma Level 2 (Lot: ____ N1190272)	--	2.3	--	2.0	PASS

KIT COMPONENTS:

NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N1290520	8 mL
COATEST APC Resistance APTT reagent	N0100837	16 mL
COATEST APC Resistance APC/CaCl2	N0101559	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.

PREPARED BY: Nehal Patel *N.M. Patel*
 PRINT SIGNATURE

2-19-20
 DATE: 2/19/2020

TITLE: Senior QC Analyst

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

2/19/2020
 DATE: 2/19/2020

TITLE: Technical Supervisor