

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
A Werfen Company


PRODUCT NAME:	COATEST APC Resistance Kit	EXPIRATION DATE:	2022-02
PRODUCT NUMBER:	82264363		
LOT NUMBER :	N0806730		

TEST DESCRIPTION	SPECIFICATIONS		UNITS	RESULTS	Pass/Fail
	MIN	MAX			
APC-ratio on ACL					
Control Plasma Level 1 (Lot: ____ N0789024	3.5	4.4	--	4.2	Pass
Control Plasma Level 2 (Lot: ____ N1190272	--	2.3	--	2.0	Pass

KIT COMPONENTS:


NAME	LOT NUMBER	VOLUME
COATEST APC Resistance CaCl2	N0806395	8 mL
COATEST APC Resistance APTT reagent	N0806398	16 mL
COATEST APC Resistance APC/CaCl2	N0806729	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: D.Tencza 
 PRINT SIGNATURE

DATE: 9/10/20
 9/10/2020

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz 
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DATE: 9/10/20
 9/10/2020

TITLE: Technical Supervisor