

CERTIFICATE OF ANALYSIS

CHROMOGENIX

Instrumentation
Laboratory
A Werfen Company

| | | | |
|-----------------|----------------------------|------------------|---------|
| PRODUCT NAME: | COATEST APC Resistance V-S | EXPIRATION DATE: | 2022-12 |
| PRODUCT NUMBER: | 82313863 | | |
| LOT: | N0613711 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | Pass/Fail |
|--------------------------------|----------------|-----|---------|---------|-----------|
| | MIN | MAX | | | |
| APT-time on ACL | | | | | |
| Diluted Control Plasma Level 1 | 26 | 46 | seconds | 32 | PASS |
| Diluted Control Plasma Level 2 | 27 | 47 | seconds | 34 | PASS |

| APC-V ratio on ACL | | | | | |
|------------------------|-----|-----|-------|---------|-----------|
| | MIN | MAX | UNITS | RESULTS | Pass/Fail |
| Control Plasma Level 1 | 2.8 | 3.2 | -- | 3.2 | PASS |
| Control Plasma Level 2 | 1.4 | 1.9 | -- | 1.9 | PASS |


KIT COMPONENTS:

| NAME | LOT NUMBER | VOLUME |
|---|------------|--------|
| COATEST APC Resistance CaCl2 | N0513393 | 2 mL |
| COATEST APC Resistance APTT reagent | N0613529 | 4 mL |
| COATEST APC Resistance APC/CaCl2 | N0613709 | 2 mL |
| COATEST APC Resistance Control Plasma Level 1 | N0613710 | 1 mL |
| COATEST APC Resistance Control Plasma Level 2 | N0513392 | 1 mL |
| COATEST APC Resistance V-DEF Plasma | N0513027 | 4 mL |

We hereby certify that the above product(s):

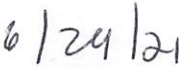
- have been manufactured and tested according to the requirements of their Manufacturing and Quality Control procedures and have been found to meet all conditions set forth with these documents;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

PREPARED BY: D. Tenaja 
 PRINT SIGNATURE

DATE: 6/29/2021 

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: D. Hazy 
 PRINT SIGNATURE

DATE: 6/29/2021 

TITLE: Technical Supervisor