

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

| | | | |
|-----------------|--------------------------|------------------|---------|
| PRODUCT NAME: | COATEST APC Resistance V | EXPIRATION DATE: | 2022-12 |
| PRODUCT NUMBER: | 82312063 | | |
| LOT NUMBER: | N0613567 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | Pass/Fail |
|--------------------------------|----------------|-----|---------|---------|-----------|
| | MIN | MAX | | | |
| Diluted Control Plasma Level 1 | 26 | 46 | seconds | 31 | PASS |
| Diluted Control Plasma Level 2 | 27 | 47 | seconds | 33 | PASS |

| APC-V ratio on ACL | | | | | |
|------------------------|-----|-----|-------|---------|-----------|
| | MIN | MAX | UNITS | RESULTS | Pass/Fail |
| 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 | N0513391 | 8 mL |
| COATEST APC Resistance APTT reagent | N0613526 | 16 mL |
| COATEST APC Resistance APC/CaCl2 | N0613542 | 2 mL |
| COATEST APC Resistance Control Plasma Level 1 | N0613566 | 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.Tencza *D. Tencza* DATE: 6/29/2021 *6/29/21*
 PRINT SIGNATURE

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: D.Harz *Debra Harz* DATE: 6/29/2021 *6/29/21*
 PRINT SIGNATURE

TITLE: Technical Supervisor