

CERTIFICATE OF ANALYSIS

CHROMOGENIX

**Instrumentation
Laboratory**
A Werfen Company

| | | | |
|-----------------|----------------------------|------------------|---------|
| PRODUCT NAME: | COATEST APC Resistance V-S | EXPIRATION DATE: | 2021-04 |
| PRODUCT NUMBER: | 82313863 | | |
| LOT: | N1199757 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | | RESULTS | Pass/Fail |
|--------------------------------|----------------|-----|---------|---------|-----------|
| | MIN | MAX | UNITS | | |
| Diluted Control Plasma Level 1 | 31 | 46 | seconds | 31 | PASS |
| Diluted Control Plasma Level 2 | 30 | 50 | seconds | 33 | PASS |

| APC-V ratio on ACL | | | | | |
|------------------------|-----|-----|----|-----|------|
| Control Plasma Level 1 | 2.8 | 3.2 | -- | 2.8 | PASS |
| Control Plasma Level 2 | 1.4 | 1.9 | -- | 1.7 | PASS |

KIT COMPONENTS:

| NAME | LOT NUMBER | VOLUME |
|---|------------|--------|
| COATEST APC Resistance CaCl ₂ | N1099586 | 2 mL |
| COATEST APC Resistance APTT reagent | N1099585 | 4 mL |
| COATEST APC Resistance APC/CaCl ₂ | N1199755 | 2 mL |
| COATEST APC Resistance Control Plasma Level 1 | N1199756 | 1 mL |
| COATEST APC Resistance Control Plasma Level 2 | N0898224 | 1 mL |
| COATEST APC Resistance V-DEF Plasma | N1098981 | 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: Nehal Patel *N.M. Patel*
 PRINT SIGNATURE
 TITLE: Senior QC Analyst

DATE: 11/25/19
 11/25/2019

APPROVAL SIGNATURE: Debra Lee Harz *Debra Lee Harz*
 PRINT SIGNATURE
 TITLE: Technical Supervisor

DATE: 11/25/19
 11/25/2019