

CERTIFICATE OF ANALYSIS

CHROMOGENIX **werfen**

| | | | |
|-----------------|----------------------------|------------------|------------|
| PRODUCT NAME: | COATEST APC Resistance V-S | EXPIRATION DATE: | 2027-06-30 |
| PRODUCT NUMBER: | 00082313863 | | |
| LOT: | N0160244 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | | RESULTS | Pass/Fail |
|--------------------------------|----------------|-----|---------|---------|-----------|
| | MIN | MAX | UNITS | | |
| APT-time on ACL | | | | | |
| Diluted Control Plasma Level 1 | 27 | 43 | seconds | 35 | PASS |
| Diluted Control Plasma Level 2 | 28 | 48 | seconds | 36 | PASS |

| APC-V ratio on ACL | | | | | |
|------------------------|-----|-----|----|-----|------|
| Control Plasma Level 1 | 2.8 | 3.2 | -- | 3.0 | PASS |
| Control Plasma Level 2 | 1.4 | 1.9 | -- | 1.8 | PASS |

KIT COMPONENTS:

| NAME | LOT NUMBER | VOLUME |
|---|------------|--------|
| COATEST APC Resistance CaCl2 | N1258726 | 2 mL |
| COATEST APC Resistance APTT reagent | N1258728 | 4 mL |
| COATEST APC Resistance APC/CaCl2 | N0169890 | 2 mL |
| COATEST APC Resistance Control Plasma Level 1 | N0169897 | 1 mL |
| COATEST APC Resistance Control Plasma Level 2 | N0169611 | 1 mL |
| COATEST APC Resistance V-DEF Plasma | N1259082 | 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.

PREPARED BY:

Monika Skopronska *Monika Skopronska*
 PRINT SIGNATURE

DATE: 2-9-26
 2/9/2026

TITLE: QC Analyst II

APPROVAL SIGNATURE:

Nehal Patel *N.M. Patel*
 PRINT SIGNATURE

DATE: 2-9-26
 2/9/2026

TITLE: Senior Group Leader