

CERTIFICATE OF ANALYSIS

CHROMOGENIX **werfen**

| | | | |
|-----------------|--------------------------|------------------|------------|
| PRODUCT NAME: | COATEST APC Resistance V | EXPIRATION DATE: | 2026-09-30 |
| PRODUCT NUMBER: | 00082312053 | | |
| LOT NUMBER: | N0351161 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | Pass/Fail |
|--------------------------------|----------------|-----|---------|---------|-----------|
| APT-time on ACL | MIN | MAX | | | |
| Diluted Control Plasma Level 1 | 28 | 44 | seconds | 32 | PASS |
| Diluted Control Plasma Level 2 | 30 | 50 | seconds | 34 | PASS |

| | | | | | |
|------------------------|-----|-----|----|-----|------|
| APC-V ratio on ACL | | | | | |
| Control Plasma Level 1 | 2.8 | 3.2 | -- | 3.1 | PASS |
| Control Plasma Level 2 | 1.4 | 1.9 | -- | 1.9 | PASS |

KIT COMPONENTS:

| NAME | LOT NUMBER | VOLUME |
|---|------------|--------|
| COATEST APC Resistance CaCl ₂ | N0350849 | 8 mL |
| COATEST APC Resistance APTT reagent | N0350844 | 16 mL |
| COATEST APC Resistance APC/CaCl ₂ | N0351157 | 2 mL |
| COATEST APC Resistance Control Plasma Level 1 | N0351160 | 1 mL |
| COATEST APC Resistance Control Plasma Level 2 | N0250218 | 1 mL |
| COATEST APC Resistance V-DEF Plasma | N0350657 | 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 Skowronska
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Monika Skowronska
SIGNATURE

DATE: 4/17/2025

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel
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N.m. Patel
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DATE: 4-17-25

TITLE: Senior Group Leader