# CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

| | | | |
|---|---|---|---|
| PRODUCT NAME: | S-2238, 25 mg Substrate | EXPIRATION DATE: | 2029-08-31 |
| PRODUCT NUMBER: | 00082032439 | | |
| LOT NUMBER: | N0866470 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | | RESULTS | DISPOSITION |
|---|---|---|---|---|---|
| | MIN | MAX | UNITS | | PASS/FAIL |
| SUBSTRATE CONCENTRATION | 23.7 | 26.3 | mg/vial | 25.0 | PASS |
| FREE p-NITROANILINE | 0 | 0.5 | mol % | 0.1 | PASS |

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: Angel Thomas (PRINT) ANGEL THOMAS (SIGNATURE) DATE: 9/4/2026 9/4/2026

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel (PRINT) N.M. Patel (SIGNATURE) DATE: 9/4/2026 9-4-26

TITLE: Senior Group Leader

# 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 | |
|---|---|---|---|---|---|
| **APT-time on ACL** | **MIN** | **MAX** | **UNITS** | | **Pass/Fail** |
| 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 Skowronska Monika Skowronska DATE: 2-9-26 2/9/2026

PRINT SIGNATURE

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel N.M. Patel DATE: 2/9/2026 2-9-26

PRINT SIGNATURE

TITLE: Senior Group Leader



526 Route 303, Orangeburg, New York 10962, Telephone 845-365-8000

# CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

| | | | |
|---|---|---|---|
| PRODUCT NAME: | S-2288, 25 mg Substrate | EXPIRATION DATE: | 2028-12-31 |
| PRODUCT NUMBER: | 00082085239 | | |
| LOT NUMBER: | N1258732 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | | RESULTS | DISPOSITION |
|---|---|---|---|---|---|
| | MIN | MAX | UNITS | | PASS/FAIL |
| SUBSTRATE CONCENTRATION | 23.7 | 26.3 | mg/vial | 24.8 | PASS |
| FREE p-NITROANILINE | 0 | 0.5 | mol % | 0.5 | PASS |

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: Fabiha Bushra (PRINT) Fabiha Bushra (SIGNATURE) DATE: 1/20/2026 1/20/26

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel (PRINT) N. M. Patel (SIGNATURE) DATE: 1/20/2026 1-20-26

TITLE: Senior Group Leader



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CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

| | | | |
|---|---|---|---|
| PRODUCT NAME: | CoaTest SP4 FVIII Kit | EXPIRATION DATE: | 2028-01-31 |
| PRODUCT NUMBER: | 00082409463 | | |
| LOT NUMBER: | N0160096 | | |

| TEST DESCRIPTION | | SPECIFICATIONS | | | RESULTS | DISPOSITION |
|---|---|---|---|---|---|---|
| | | MIN | MAX | UNITS | | PASS/FAIL |
| **Coatest SP4 Factor VIII Kit (00082409463)** | | | | | | |
| **High Range** | | | | | | |
| | Slope | 0.0077 | 0.0112 | -- | 0.0087 | PASS |
| | Intercept | -- | 0.250 | -- | 0.071 | PASS |
| | Standard Curve (r) | 0.99 | -- | -- | 1.000 | PASS |
| **Low Range** | | | | | | |
| | Slope | 0.020 | 0.060 | -- | 0.041 | PASS |
| | Intercept | -- | 0.406 | -- | 0.092 | PASS |
| | Standard Curve (r) | 0.99 | -- | -- | 0.997 | PASS |

**KIT COMPONENTS:**

| DESCRIPTION | LOT NUMBER | VOLUME |
|---|---|---|
| COATEST SP FVIII CACL2 | N0169384 | 6 mL |
| COATEST SP FVIII FACTOR IXa + FACTOR X | N0160082 | 3 mL |
| COATEST SP FVIII S-2765 + I-2581 | N0160064 | 12 mL |
| COATEST SP FVIII BUFFER | N0160079 | 20 mL |
| COATEST SP FVIII PHOSPHOLIPID | N0261115 | 2 mL |

PREPARED BY: Monika Skowronska (PRINT) Monika Skowronska (SIGNATURE) DATE: 3/24/2026 3-24-26

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel (PRINT) N.M.Patel (SIGNATURE) DATE: 3/24/2026 3.24.26

TITLE: Senior Group Leader



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# CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

| | | | |
|---|---|---|---|
| PRODUCT NAME: | FXa, 10 x 71 nkat | EXPIRATION DATE: | 2028-09-30 |
| PRODUCT NUMBER: | 00082098539 | | |
| LOT NUMBER: | N0361767 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | | RESULTS | DISPOSITION |
|---|---|---|---|---|---|
| | MIN | MAX | UNITS | | PASS/FAIL |
| **FACTOR Xa, 71 nkat (650515)** | | | | | |
| ACTIVITY | 61 | 81 | nkat/vial | 76 | PASS |
| STANDARD CURVE ($r^2$) | 0.990 | 1.000 | -- | 1.000 | PASS |
| CONTROL RECOVERY | 66.7 | 73.7 | nkat/vial | 72.2 | PASS |

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;

4-10-26

PREPARED BY: Monika Skowronska (PRINT) Monika Skowronska (SIGNATURE) DATE: 4/10/2026

TITLE: QC Analyst III

APPROVAL SIGNATURE: Nehal Patel (PRINT) N.M. Patel (SIGNATURE) DATE: 4/10/2026 4-10-26

TITLE: Senior Group Leader



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CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

| | | | |
|---|---|---|---|
| PRODUCT NAME: | S-2302, 25 mg Substrate | EXPIRATION DATE: | 2029-11-30 |
| PRODUCT NUMBER: | 00082034039 | | |
| LOT NUMBER: | N0765789 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | | RESULTS | DISPOSITION |
|---|---|---|---|---|---|
| | MIN | MAX | UNITS | | PASS/FAIL |
| SUBSTRATE CONCENTRATION | 23.7 | 26.3 | mg/vial | 25.2 | PASS |
| FREE p-NITROANILINE | 0 | 0.5 | mol % | 0 | PASS |

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: Girlie Reinoso (PRINT) G. Reinoso (SIGNATURE) DATE: 8/11/2026 8/11/26

TITLE: QC Analyst III

APPROVAL SIGNATURE: Monika Skowronska (PRINT) Monika Skowronska (SIGNATURE) DATE: 8/11/2026 8-11-26

TITLE: QC Analyst III



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# CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

| | | | |
|---|---|---|---|
| PRODUCT NAME: | S-2765, 25 mg Substrate | EXPIRATION DATE: | 2029-05-31 |
| PRODUCT NUMBER: | 00082141339 | | |
| LOT: | N0563944 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | | RESULTS | DISPOSITION |
|---|---|---|---|---|---|
| | MIN | MAX | UNITS | | PASS/FAIL |
| SUBSTRATE CONCENTRATION | 23.7 | 26.3 | mg/vial | 25.4 | PASS |
| FREE p-NITROANILINE | 0 | 0.5 | mol % | 0.2 | PASS |

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: Girlie Reinoso (PRINT) G. Reinoso (SIGNATURE) DATE: 6/12/26 6/12/2026

TITLE: QC Analyst III

APPROVAL SIGNATURE: Nehal Patel (PRINT) N.M. Patel (SIGNATURE) DATE: 6-12-26 6/12/2026

TITLE: Senior Group Leader



526 Route 303, Orangeburg, New York 10962, Telephone 845-365-8000

# CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

| | | |
|---|---|---|
| PRODUCT NAME: | COATEST APC Resistance Control Plasma Level 2 | EXPIRATION DATE: 2028-06-30 |
| PRODUCT NUMBER: | 00082266863 | |
| LOT NUMBER: | N0664644 | |

| TEST DESCRIPTION | | SPECIFICATIONS | | | RESULTS | DISPOSITION |
|---|---|---|---|---|---|---|
| Analysis with COATEST APC R V: | | MIN | MAX | UNITS | | PASS/FAIL |
| APT Time | $CaCl_2$ | 28 | 41 | seconds | 35 | PASS |
| APC Ratio | | 1.4 | 1.9 | -- | 1.8 | PASS |

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 (PRINT) Monika Skowronska (SIGNATURE) DATE: 7/9/2026 7-9-26

TITLE: QC Analyst III

APPROVAL SIGNATURE: Nehal Patel (PRINT) N.M.Patel (SIGNATURE) DATE: 7/9/2026 7-9-26

TITLE: Senior Group Leader



526 Route 303, Orangeburg, New York 10962, Telephone 845-365-8000

# CERTIFICATE OF ANALYSIS

CHROMOGENIX werfen

| | | | |
|---|---|---|---|
| PRODUCT NAME: | COATEST SP FVIII | EXPIRATION DATE: | 2028-02-29 |
| PRODUCT NUMBER: | 00082408663 | | |
| LOT NUMBER : | N0361946 | | |

| TEST DESCRIPTION | | SPECIFICATIONS MIN | SPECIFICATIONS MAX | UNITS | RESULTS | DISPOSITION PASS/FAIL |
|---|---|---|---|---|---|---|
| **High Range** | | | | | | |
| | Slope | 0.0077 | 0.0112 | -- | 0.0095 | PASS |
| | Intercept | -- | 0.250 | -- | 0.083 | PASS |
| | Standard Curve (r) | 0.99 | -- | -- | 0.999 | PASS |
| **Low Range** | | | | | | |
| | Slope | 0.020 | 0.060 | -- | 0.042 | PASS |
| | Intercept | -- | 0.406 | -- | 0.090 | PASS |
| | Standard Curve (r) | 0.99 | -- | -- | 0.998 | PASS |

**KIT COMPONENTS:**

| NAME | LOT NUMBER | VOLUME |
|---|---|---|
| COATEST SP FVIII CaCl2 | N0260988 | 6 mL |
| COATEST SP FVIII Factor IXa + Factor X | N0855808 | 10 mL |
| COATEST SP FVIII S-2765 + I-2581 | N0261002 | 12 mL |
| COATEST SP FVIII Buffer, stock solution | N0261066 | 20 mL |
| COATEST SP FVIII Phospholipid | N0260998 | 2 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 Monika Skowronska DATE: 4-3-26 04/03/26
PRINT SIGNATURE

TITLE QC Analyst III

APPROVAL SIGNATURE: N.M.Patel Nehal Patel DATE: 4.3.26 04/03/26
PRINT SIGNATURE

TITLE Senior Group Leader