

CERTIFICATE OF ANALYSIS

# CHROMOGENIX *werfen*

|                 |                       |                  |            |
|-----------------|-----------------------|------------------|------------|
| PRODUCT NAME:   | CoaTest SP4 FVIII Kit | EXPIRATION DATE: | 2026-11-30 |
| PRODUCT NUMBER: | 00082409463           |                  |            |
| LOT NUMBER:     | N1147744              |                  |            |

| TEST DESCRIPTION                          | SPECIFICATIONS |        | UNITS | RESULTS | DISPOSITION |
|---|----------------|--------|-------|---------|-------------|
|   | MIN            | MAX    |       |         |             |
| Coatest SP4 Factor VIII Kit (00082409463) |                |        |       |         |             |
| <b>High Range</b>                         |                |        |       |         |             |
| Slope                                     | 0.0077         | 0.0112 | --    | 0.0105  | PASS        |
| Intercept                                 | --             | 0.250  | --    | 0.134   | PASS        |
| Standard Curve (r)                        | 0.99           | --     | --    | 0.999   | PASS        |
| <b>Low Range</b>                          |                |        |       |         |             |
| Slope                                     | 0.020          | 0.060  | --    | 0.052   | PASS        |
| Intercept                                 | --             | 0.406  | --    | 0.229   | PASS        |
| Standard Curve (r)                        | 0.99           | --     | --    | 0.998   | PASS        |

**KIT COMPONENTS:**

| DESCRIPTION                            | LOT NUMBER | VOLUME |
|--|------------|--------|
| COATEST SP FVIII CACL2                 | N1147742   | 6 mL   |
| COATEST SP FVIII FACTOR IXa + FACTOR X | N1147735   | 3 mL   |
| COATEST SP FVIII S-2765 + I-2581       | N0250405   | 12 mL  |
| COATEST SP FVIII BUFFER                | N1147743   | 20 mL  |
| COATEST SP FVIII PHOSPHOLIPID          | N1147724   | 2 mL   |

PREPARED BY: Monika Skowronska *Monika Skowronska*  
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DATE: 3/20/2025 *3-20-25*

TITLE: QC Analyst II

APPROVAL SIGNATURE: Nehal Patel *N.m. Patel*  
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DATE: 3/20/2025 *3.20.25*

TITLE: Senior Group Leader