

CERTIFICATE OF ANALYSIS

**CHROMOGENIX**

**Instrumentation  
Laboratory**  
A Werfen Company

|                 |                       |                  |         |
|-----------------|-----------------------|------------------|---------|
| PRODUCT NAME:   | CoaTest SP4 FVIII Kit | EXPIRATION DATE: | 2022-04 |
| PRODUCT NUMBER: | 82409463              |                  |         |
| LOT NUMBER:     | N0504529              |                  |         |

| TEST DESCRIPTION                              | SPECIFICATIONS     |        |        | RESULTS | DISPOSITION |      |
|---|--------------------|--------|--------|---------|-------------|------|
|   | MIN                | MAX    | UNITS  |         |             |      |
| <b>Coatest SP4 Factor VIII Kit (82409463)</b> |                    |        |        |         |             |      |
| High Range                                    | Slope              | 0.0077 | 0.0112 | --      | 0.0090      | PASS |
|   | Intercept          | --     | 0.250  | --      | 0.132       | PASS |
|   | Standard Curve (r) | 0.99   | --     | --      | 0.998       | PASS |
| Low Range                                     | Slope              | 0.020  | 0.060  | --      | 0.043       | PASS |
|   | Intercept          | --     | 0.406  | --      | 0.155       | PASS |
|   | Standard Curve (r) | 0.99   | --     | --      | 1.000       | PASS |

**KIT COMPONENTS:**

| DESCRIPTION                            | LOT NUMBER | VOLUME |
|--|------------|--------|
| COATEST SP FVIII CACL2                 | N0403790   | 6 mL   |
| COATEST SP FVIII FACTOR IXa + FACTOR X | N0403543   | 3 mL   |
| COATEST SP FVIII S-2765 + I-2581       | N0403541   | 12 mL  |
| COATEST SP FVIII BUFFER                | N0504270   | 20 mL  |
| COATEST SP FVIII PHOSPHOLIPID          | N0403793   | 2 mL   |

PREPARED BY: Nehal Patel N.M. Patel  
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DATE: 6/4/2020 6-4-20

TITLE: Senior QC Analyst

APPROVAL SIGNATURE: Debra Lee Harz Debra Lee Harz  
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DATE: 6/4/2020 6/4/20

TITLE: Technical Supervisor