

CERTIFICATE OF ANALYSIS

CHROMOGENIX



| | | | |
|-----------------|-----------------|------------------|---------|
| PRODUCT NAME: | COATEST Heparin | EXPIRATION DATE: | 2023-09 |
| PRODUCT NUMBER: | 25553963 | | |
| LOT NUMBER: | N0311869 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | DISPOSITION |
|----------------------------------|----------------|-------|-----------|---------|-------------|
| | MIN | MAX | | | |
| A. FACTOR Xa | | | | | |
| ACTIVITY | 61 | 81 | nkat/vial | 72 | PASs |
| STANDARD CURVE (r ²) | 0.990 | 1.000 | -- | 0.999 | PASS |
| CONTROL RECOVERY | 65.7 | 72.7 | nkat/vial | 70.8 | PASS |
| RESIDUAL MOISTURE (KF) | 0 | 5 | % | NA | |
| RESIDUAL MOISTURE (FMS) | 0 | 12.0 | Torr | 0.5 | PASS |

| B. S-2222, FOR COATEST HEPARIN | | | | | |
|---------------------------------------|-------|------|---------|-------|------|
| SUBSTRATE CONCENTRATION | 14.25 | 16.2 | mg/vial | 15.56 | PASS |
| FREE p-NITROANILINE | 0 | 0.5 | mol % | 0 | PASS |
| RESIDUAL MOISTURE | 0 | 5 | % | 0.6 | PASS |

| C. ANTITHROMBIN 10 IU, FOR COATEST HEPARIN | | | | | |
|---|---|----|---------|----|------|
| ANTITHROMBIN ACTIVITY | 9 | 11 | IU/vial | 10 | PASS |

| D. NORMAL CONTROL PLASMA | | | | | |
|--|-------------------------------------|--------|-------|--------|------|
| HEPARIN ANTAGONISTS | 0 | < 0.10 | IU/mL | 0 | PASS |
| STANDARD CURVE: | | | | | |
| regression coefficient (r ²) | 0.99 | 1.00 | -- | 0.992 | PASS |
| slope | -0.800 | -0.500 | -- | -0.657 | PASS |
| intercept | 0.650 | 1.030 | -- | 0.716 | PASS |
| CONTROL RECOVERY | 0.4 | 0.6 | IU/mL | 0.6 | PASS |
| ABSORBANCE AT 405nm | 0.00 | 0.400 | -- | 0.221 | PASS |
| APPEARANCE | yellowish-white, lyophilized powder | | | PASS | PASS |

| E. BUFFER pH 8.4 CONC., FOR COATEST HEPARIN | | | | | |
|--|---------------------------|-----|----|------|------|
| APPEARANCE | clear, colorless solution | | | PASS | PASS |
| pH @ 20 - 25°C | 8.3 | 8.5 | -- | 8.5 | PASS |

| F. COATEST HEPARIN KIT | | | | | |
|--|--------|--------|-------|--------|------|
| SLOPE | -0.800 | -0.500 | -- | -0.715 | PASS |
| INTERCEPT | 0.650 | 1.030 | -- | 0.727 | PASS |
| REGRESSION COEFFICIENT (r ²) | 0.99 | 1.00 | | 0.99 | PASS |
| CONTROL RECOVERY | 0.4 | 0.6 | IU/mL | 0.6 | PASS |

KIT COMPONENTS:

| NAME | LOT NUMBER | VOLUME |
|-------------------------------|------------|--------|
| COATEST HEPARIN FACTOR Xa | N0311444 | 2 mL |
| COATEST HEPARIN S-2222 | N0311868 | 4 mL |
| COATEST ANTITHROMBIN | N0311306 | 1 mL |
| COATEST HEPARIN NORMAL PLASMA | N0311699 | 1 mL |
| COATEST HEPARIN BUFFER | N0311701 | 12 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;
- meet all applicable requirements of the 98/79/EC Directive according to which they are CE marked.

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DATE: 4-16-21

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APPROVAL SIGNATURE: Debra Harz
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