

CERTIFICATE OF ANALYSIS

CHROMOGENIX

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|-------------------------------------------|--------------------------------|
| PRODUCT: <u>COAMATIC HEPARIN</u> | PRODUCT #: <u>82339363</u> |
| EXP. DATE: <u>2017-10</u> | LOT #: <u>N1159386</u> |
| VENDOR: <u>INSTRUMENTATION LABORATORY</u> | ASSAYED PER QCM: <u>823393</u> |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | DISPOSITION |
|----------------------------------|----------------|-------|-----------|---------|-------------|
| | MIN | MAX | | | PASS/FAIL |
| A. FACTOR Xa (H01382) | | | | | |
| pH | 7.9 | 8.1 | pH | 7.9 | PASS |
| ACTIVITY | 31.5 | 38.5 | nkat/vial | 37.3 | PASS |
| STANDARD CURVE (r ²) | 0.990 | 1.000 | -- | 0.998 | PASS |
| CONTROL RECOVERY | 67.5 | 74.6 | nkat/vial | 72.2 | PASS |

| B. S-2732, FOR COAMATIC HEPARIN (H01391) | | | | | |
|-------------------------------------------------|------|------|---------|------|------|
| SUBSTRATE CONCENTRATION | 14.3 | 15.7 | mg/vial | 14.3 | PASS |
| FREE p-NITROANILINE | 0 | 0.5 | mol % | 0 | PASS |

| C. COAMATIC HEPARIN KIT (082339363) - LMW HEPARIN ON TOP | | | | | |
|-----------------------------------------------------------------|--------|--------|----|---------|------|
| SLOPE | -0.351 | -0.103 | -- | -0.2169 | PASS |
| r ² | 0.985 | -- | -- | 0.994 | PASS |

| D. COAMATIC HEPARIN KIT (082339363) - UNFRACTIONATED HEPARIN ON TOP | | | | | |
|----------------------------------------------------------------------------|--------|--------|----|---------|------|
| SLOPE | -0.336 | -0.114 | -- | -0.1948 | PASS |
| r ² | 0.985 | -- | -- | 0.987 | PASS |

Kit Components:

| Name | Lot Number | Exp. date | Volume |
|-----------|------------|-----------|------------|
| Factor Xa | N1059104 | 2017-10 | 1 ml (x 2) |
| S-2732 | N1059101 | 2017-10 | 2 ml (x 2) |

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.

PREPARED BY:

N. Patel

DATE: 11/16/2015

APPROVAL SIGNATURE:

D. Tencza

DATE: 11/16/2015