

CERTIFICATE OF ANALYSIS

CHROMOGENIX

| | | |
|------------------------------------|----------------------|------------------------|
| PRODUCT: COAMATIC Protein C | Recording of Results | 82209863 |
| EXP. DATE: 2016-08 | Lot #: | N0942356 |
| VENDOR: INSTRUMENTATION LABORATORY | Assayed per QCM: | 822098/822106/49730500 |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | DISPOSITION PASS/FAIL |
|--|----------------|--------|-------|---------|--------------------------|
| | MIN | MAX | | | |
| A. Protein C Activator (H00749) | | | | | |
| ACTIVITY VS. REFERENCE LOT | 90 | 110 | % | 103 | Pass |
| SLOPE | 0.0010 | 0.0015 | -- | 0.0012 | Pass |
| INTERCEPT | - | 0.010 | - | 0.002 | Pass |
| REGRESSION COEFFICIENT | 0.990 | - | - | 1.000 | Pass |
| CONTROL PLASMAS: | | | | | |
| NORMAL | 88 | 118 | % | 102 | Pass |
| SPECIAL TEST LEVEL I | 45 | 65 | % | 50 | Pass |
| SPECIAL TEST LEVEL II | 15 | 35 | % | 24 | Pass |

| B. S-2366/ I-2581 For Coamatic Protein C (H00163) | | | | | |
|--|-----|-----|---------|-----|------|
| SUBSTRATE CONCENTRATION | 5.4 | 6.6 | mg/vial | 6.0 | Pass |
| FREE p-NITROANILINE | 0 | 0.5 | mol % | 0.1 | Pass |

| C. COAMATIC PROTEIN C KIT (0822098) | | | | | |
|--|--------|--------|----|--------|------|
| SLOPE | 0.0010 | 0.0015 | -- | 0.0012 | Pass |
| INTERCEPT | -- | 0.010 | - | 0.003 | Pass |
| REGRESSION COEFFICIENT | 0.990 | - | - | 0.999 | Pass |
| CONTROL PLASMA | | | | | |
| NORMAL | 88 | 118 | % | 110 | Pass |
| SPECIAL TEST LEVEL I | 45 | 65 | % | 58 | Pass |
| SPECIAL TEST LEVEL II | 15 | 35 | % | 25 | Pass |

| KIT COMPONENTS : | | | |
|-------------------------|------------|-----------|------------|
| NAME | LOT NUMBER | EXP. DATE | VOLUME |
| Protein C Activator | N0842038 | 2016-08 | 2 ml (x 2) |
| S-2366/I-2581 | N0841683 | 2016-08 | 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: Maria Ottlinger DATE: 9-22-14

APPROVAL SIGNATURE: P. Ronza DATE: 9-23-14