

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
 A Werfen Company

| | | | |
|-----------------|--------------------|------------------|---------|
| PRODUCT NAME: | COAMATIC Protein C | EXPIRATION DATE: | 2020-02 |
| PRODUCT NUMBER: | 82209863 | | |
| LOT | N0286038 | | |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | DISPOSITION |
|----------------------------------------|----------------|--------|-------|---------|-------------|
| | MIN | MAX | | | |
| A. Protein C Activator (H00749) | | | | | |
| ACTIVITY VS. REFERENCE LOT | 90 | 110 | % | 100 | PASS |
| SLOPE | 0.0010 | 0.0015 | -- | 0.0013 | PASS |
| INTERCEPT | -- | 0.010 | -- | 0.003 | PASS |
| REGRESSION COEFFICIENT | 0.990 | -- | -- | 0.999 | PASS |
| CONTROL PLASMAS: | | | | | |
| NORMAL | 88 | 118 | % | 103 | PASS |
| SPECIAL TEST LEVEL I | 49 | 69 | % | 54 | PASS |
| SPECIAL TEST LEVEL II | 20 | 40 | % | 26 | PASS |

| B. S-2366/ I-2581 For Coamatic P protein C (H00163) | | | | | |
|------------------------------------------------------------|-----|-----|---------|-----|------|
| SUBSTRATE CONCENTRATION | 5.4 | 6.6 | mg/vial | 5.7 | PASS |
| FREE p-NITROANILINE | 0 | 0.5 | mol % | 0 | PASS |

| C. COAMATIC PROTEIN C KIT (0822098) | | | | | |
|--------------------------------------------|--------|--------|----|--------|------|
| SLOPE | 0.0010 | 0.0015 | -- | 0.0013 | PASS |
| INTERCEPT | -- | 0.010 | -- | 0.003 | PASS |
| REGRESSION COEFFICIENT | 0.990 | -- | -- | 0.999 | PASS |
| CONTROL PLASMA | | | | | |
| NORMAL | 88 | 118 | % | 101 | PASS |
| SPECIAL TEST LEVEL I | 49 | 69 | % | 52 | PASS |
| SPECIAL TEST LEVEL II | 20 | 40 | % | 25 | PASS |

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:

Nehal Patel

N.M. Patel

DATE: 3/22/2018

3-22-18

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SIGNATURE

TITLE: Senior QC Analyst

APPROVAL SIGNATURE:

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DATE: 3/22/2018

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