

CERTIFICATE OF ANALYSIS

CHROMOGENIX


**Instrumentation
Laboratory**
A Werfen Company

| | | |
|------------------|-----------------------------|---------------------------------|
| PRODUCT NAME : | <u>COAMATIC FACTOR VIII</u> | EXPIRATION DATE: <u>2020-03</u> |
| PRODUCT NUMBER : | <u>82258563</u> | |
| LOT NUMBER: | <u>N0386767</u> | |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | PASS/FAIL |
|------------------|----------------|------|-------|---------|-----------|
| | MIN | MAX | | | |
| HIGH RANGE | | | | | |
| Slope | 0.33 | 0.57 | -- | 0.44 | PASS |
| Intercept | --- | 0.12 | -- | 0.06 | PASS |
| r | 0.990 | --- | -- | 0.996 | PASS |
| LOW RANGE | | | | | |
| Slope | 2.8 | 6.9 | -- | 4.8 | PASS |
| Intercept | --- | 0.21 | -- | 0.11 | PASS |
| r | 0.990 | --- | -- | 0.998 | 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.

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|---------------------|---|---|
| PREPARED BY: | Nehal Patel N. M. Patel | DATE: 4-20-18 |
| | PRINT SIGNATURE | 4/20/2018 |
| TITLE: | Senior QC Analyst | |
| APPROVAL SIGNATURE: | Donna Tencza Donna Tencza | DATE: 4-20-18 |
| | PRINT SIGNATURE | 4/20/2018 |
| TITLE: | Senior QC Analyst | |