

CERTIFICATE OF ANALYSIS

CHROMOGENIX

| | | | |
|------------|-----------------------------------|------------------|------------------------|
| PRODUCT: | <u>COAMATIC FACTOR VIII</u> | PRODUCT # : | <u>82258563</u> |
| EXP. DATE: | <u>2017-08</u> | LOT # : | <u>N0857818</u> |
| VENDOR: | <u>INSTRUMENTATION LABORATORY</u> | ASSAYED PER QCM: | <u>822585/49730503</u> |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | PASS/FAIL |
|------------------|----------------|------|-------|---------|-----------|
| | MIN | MAX | | | |
| HIGH RANGE | | | | | |
| Slope | 0.33 | 0.51 | -- | 0.49 | PASS |
| Intercept | -- | 0.12 | -- | 0.06 | PASS |
| r ² | 0.990 | -- | -- | 0.996 | PASS |
| LOW RANGE | | | | | |
| Slope | 2.8 | 5.8 | -- | 5.4 | PASS |
| Intercept | -- | 0.18 | -- | 0.13 | PASS |
| r ² | 0.990 | -- | -- | 1.000 | PASS |

Kit Components:

| Name | Lot Number | Exp. date |
|----------------|------------|-----------|
| S-2765/ I-2581 | N0857817 | 2017-08 |
| Factor Reagent | N0857796 | 2017-08 |
| Buffer | N0857795 | 2017-08 |

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: NPATEL DATE: 8/26/2015

APPROVAL SIGNATURE: DTENCZA DATE: 8/26/2015