



Certificate of Analysis

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|--------------------------------------|-------------------------|
| PRODUCT: CoaTest SP Factor FVIII Kit | PRODUCT # : 82408663 |
| EXP. DATE: 2019-06 | LOT # : N0770961 |
| VENDOR: INSTRUMENTATION LABORATORY | ASSAYED PER QCM: 824086 |

| TEST DESCRIPTION | SPECIFICATIONS | | UNITS | RESULTS | DISPOSITION |
|----------------------------------------------|----------------|--------|-------|---------|-------------|
| | MIN | MAX | | | |
| Coatest SP Factor VIII Kit (82103363) | | | | | |
| High Range | | | | | |
| Slope | 0.0077 | 0.0112 | -- | 0.0083 | PASS |
| Intercept | -- | 0.250 | -- | 0.118 | PASS |
| Standard Curve (r) | 0.99 | -- | -- | 0.997 | PASS |
| Low Range | | | | | |
| Slope | 0.020 | 0.060 | -- | 0.037 | PASS |
| Intercept | -- | 0.406 | -- | 0.142 | PASS |
| Standard Curve (r) | 0.99 | -- | -- | 0.998 | PASS |

| KIT COMPONENTS : | | | |
|----------------------|------------|-----------|--------|
| NAME | LOT NUMBER | EXP. DATE | VOLUME |
| CaCl ₂ | N0670770 | 2020-06 | 6 ml |
| CT SP Substrate | N0670772 | 2019-06 | 12 ml |
| Factor Reagent | N0770948 | 2020-01 | 10 ml |
| CT SP Buffer, pH 7.3 | N0670624 | 2019-06 | 20 ml |
| CT SP Phospholipid | N0670769 | 2019-06 | 2 ml |

PREPARED BY:

NPATEL N.m-lad9

DATE:

07/21/17

7-21-17

APPROVAL SIGNATURE:

DTENCZA Dencza

DATE:

07/21/17

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