

ANALYSIS CERTIFICATE

BIOPHEN™ Anti-IIa (2 stages Heparin assay) - #220005

Lot : F1700343

QC Release : 2017-09-05

Expiration date : 2019-09-23

| Components | Qty | Exp. (months) | Lot # | Exp. date |
|-------------------|------------|--------------------------|--------------|----------------------|
| R1 : ATIII(h) | 2 vials | 30 | F171100343 | 2019-09-23 |
| R2 : Thrombin | 2 vials | 30 | F171100343 | 2019-11-24 |
| R3 : Substrate | 2 vials | 30 | F171100343 | 2019-11-02 |



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| Analytical data | | | | | | | | Specifications |
|--|-------|-------|-------|-------|-------|-------|----------------|---|
| 5. <u>Assay reactivity (in the tested dilution, CS-series)</u> | | | | | | | | $R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$ |
| IU/mL | 0.0 | 0.005 | 0.01 | 0.02 | 0.03 | 0.04 | R ² | |
| A405 UFH purified | 1,537 | 1,295 | 1,112 | 0,812 | 0,618 | 0,473 | 0,998 | |
| A405LMWH purified | 1,506 | 1,170 | 0,914 | 0,561 | 0,384 | 0,284 | 0,990 | |

| | | |
|---|---------------|---------------|
| 6. <u>UFH Detection threshold (concentration in the tested dilution, CS-series)</u> | | ≤ 0.005 IU/mL |
| In Purified solution | < 0,001 IU/mL | |

| | | | | | | | | | |
|---|--------|--------|--------|--------|--------|--------|----------------|-----------------|---|
| 7. <u>Stability of reconstituted reagents (purified milieu, CS-series)</u> | | | | | | | | | $R^2 \geq 0.98$ $\Delta A405 (0-0.04) \geq 0.65$ $\Delta A405 (0 IU/mL) \leq 10\%$ between fresh and stored $A405 (Free pNA) \leq 0.30$ |
| Reagents tested after 15 days at 2-8°C, or 4 days at RT (18-25°C) or Frozen ≤ -20°C | | | | | | | | | |
| A405 values for UFH | | | | | | | | | |
| UFH IU/mL | 0.0 | 0.005 | 0.01 | 0.02 | 0.03 | 0.04 | R ² | A405 (Free pNA) | |
| Freshly restored | 1,4890 | 1,2298 | 1,0421 | 0,7400 | 0,5496 | 0,4243 | 0,996 | 0,110 | |
| 15 days at 2-8°C | 1,4724 | 1,2146 | 1,0328 | 0,7399 | 0,5528 | 0,4325 | 0,996 | 0,106 | |
| 4 days at RT | 1,3843 | 1,1784 | 1,0302 | 0,7777 | 0,6099 | 0,4836 | 0,998 | 0,106 | |
| Frozen ≤ -20°C | 1,4345 | 1,1697 | 0,9995 | 0,7164 | 0,5318 | 0,4187 | 0,994 | 0,110 | |

| | |
|------------|---|
| Comments : | <input checked="" type="checkbox"/> PASSED IN COMPLIANCE |
|------------|---|

Date : 2017-09-05

QC Manager : S. LECOURT