

ANALYSIS CERTIFICATE

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

Lot : FE2813

QC Release : 1.4 AOUT 2025

Expiration date : 2027-12-03

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : ATIII(h)	2 vials	30	FE2813	2027-12-03
R2 : Thrombin	2 vials	30	FE2813	2028-01-07
R3 : Substrate	2 vials	30	FE2813	2027-12-14

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

Lot : FE2813

QC Release : .1 4 AOUT 2025

Expiration date : 2027-12-03

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

Lot : FE2813

QC Release : 14 AOUT 2025

Expiration date : 2027-12-03

Analytical data								Specifications																																													
5. Assay reactivity (in the tested dilution, CS-series) <table border="1"> <thead> <tr> <th>IU/mL</th> <th>0.0</th> <th>0.005</th> <th>0.01</th> <th>0.02</th> <th>0.03</th> <th>0.04</th> <th>R²</th> </tr> </thead> <tbody> <tr> <td>A405 UFH purified</td> <td>1.467</td> <td>1.194</td> <td>0.966</td> <td>0.621</td> <td>0.417</td> <td>0.281</td> <td>1.000</td> </tr> <tr> <td>A405LMWH purified</td> <td>1.501</td> <td>1.317</td> <td>1.125</td> <td>0.736</td> <td>0.431</td> <td>0.261</td> <td>0.990</td> </tr> </tbody> </table>								IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R ²	A405 UFH purified	1.467	1.194	0.966	0.621	0.417	0.281	1.000	A405LMWH purified	1.501	1.317	1.125	0.736	0.431	0.261	0.990	R² ≥ 0.98 ΔA405 (0-0.04) ≥ 0.65																					
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6. UFH Detection threshold (concentration in the tested dilution, CS-series) In Purified solution 0.000 IU/mL								≤ 0.005 IU/mL																																													
7. Stability of reconstituted reagents (purified milieu, CS-series) 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 <table border="1"> <thead> <tr> <th>UFH IU/mL</th> <th>0.0</th> <th>0.005</th> <th>0.01</th> <th>0.02</th> <th>0.03</th> <th>0.04</th> <th>R²</th> <th>A405 (Free pNA)</th> </tr> </thead> <tbody> <tr> <td>Freshly restored</td> <td>1.312</td> <td>1.027</td> <td>0.830</td> <td>0.522</td> <td>0.335</td> <td>0.221</td> <td>1.000</td> <td>0.104</td> </tr> <tr> <td>15 days at 2-8°C</td> <td>1.293</td> <td>1.009</td> <td>0.821</td> <td>0.517</td> <td>0.333</td> <td>0.223</td> <td>1.000</td> <td>0.102</td> </tr> <tr> <td>4 days at RT</td> <td>1.298</td> <td>1.016</td> <td>0.836</td> <td>0.528</td> <td>0.343</td> <td>0.232</td> <td>1.000</td> <td>0.104</td> </tr> <tr> <td>Frozen ≤ -20°C</td> <td>1.323</td> <td>1.033</td> <td>0.831</td> <td>0.517</td> <td>0.323</td> <td>0.213</td> <td>1.000</td> <td>0.108</td> </tr> </tbody> </table>								UFH IU/mL	0.0	0.005	0.01	0.02	0.03	0.04	R ²	A405 (Free pNA)	Freshly restored	1.312	1.027	0.830	0.522	0.335	0.221	1.000	0.104	15 days at 2-8°C	1.293	1.009	0.821	0.517	0.333	0.223	1.000	0.102	4 days at RT	1.298	1.016	0.836	0.528	0.343	0.232	1.000	0.104	Frozen ≤ -20°C	1.323	1.033	0.831	0.517	0.323	0.213	1.000	0.108	R² ≥ 0.98 ΔA405 (0-0.04) ≥ 0.65 Δ A405 (0 IU/mL) ≤ 10% between fresh and stored A405 (Free pNA) ≤ 0.30
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Comments :								☒ PASSED IN COMPLIANCE																																													

Date : 14 AOUT 2025

QC Manager : CORNU JEAN-LOUIS

Resp. Labo CQ

[Signature]