HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France

ANALYSIS CERTIFICATE

HYPHEN BioMed
A Company of Sysmex Group

BIOPHEN™ ANTI-Xa (2 Stages Heparin assay) - #221005 **Lot: FC117919**

QC Release: 2023-07-05 **Expiration date: 2025-10-14**

Components	Qty	Exp. (months)	Lot #	Exp. date
R1: ATIII(h)	2 vials	30	FC117919	2025-11-07
R2: FXa (b)	2 vials	30	FC117919	2025-11-17
R3: Substrate	2 vials	30	FC117919	2025-10-14

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Analytical data	Specifications
1. AT III(h)	
a. Lot Homogeneity (A405 for 0 IU/mL heparin) N: 20 Mean (A405): 2.014 CV: 1.1 %	≤ 5 %
b. AT content per vial (anti-Xa activity chromogenic assay) 5.55 IU	≥ 4.75 IU
c. Indicative AT content per vial (A280/Lowry on raw material) ~ 660 µg	
d. SDS PAGE (on raw material) 1 major band of about 58 000 Da	1 major band of about 58,000 Da
e. Absence of heparin (on raw material) Absence	Absence
2. FXa(b)	
a. Lot Homogeneity (A405 for 0 IU/mL heparin) N: 20 Mean (A405): 2.043 CV: 1.3 %	≤ 5 %
b. SDS PAGE (4-12% acrylamide) (FX zymogen for raw material) 1 major band of about 55 000 Da	1 major band of about 55,000 Da
c. Indicative FXa content per vial (Lowry, from zymogen raw material) ~ 84 µg/vial	
d. Chromogenic activity on Xa substrate (10µg/ml) (raw material) A405 with RVV: 1.689 A405 without RVV: 1.611	ΔA405 <10%
3. Substrate	
a. Blank value (free pNA) Mean (A405): 0.075	A405 ≤ 0.30
b. Lot Homogeneity (A405 for 0 IU/mL heparin) N: 20 Mean (A405): 2.065 CV: 1.8 %	≤ 5 %
c. Indicative content per vial (raw material) 5 mg (about 7.8 µmol)	
d. HPLC analysis purity grade (raw material) 96 %	≥ 95%
e. Experimental molecular weight (raw material) 641.7 Da	641.7 ± 5 Da

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Analytical data	Specifications

5. Assay reactivity (in the tested dilution, CS-series)

A405	IU/mL (in the tested dilution)	0.0	0.006	0.017	0.033	0.050	0.067	R^2
Purified milieu	UFH	1.196	1.081	0.871	0.603	0.399	0.269	0.99
	LMWH	0.848	0.702	0.496	0.269	0.152	0.092	1.00

Specifications: $R^2 \geq 0.98$; $\Delta A405(0\text{-}0.067) \geq 0.5$

6. Detection threshold (concentration in the tested dilution, CS-series)

In Purified solution < 0.005 IU/mL

Specifications: ≤ 0.005 IU/mL

7. Stability of reconstituted reagents (purified milieu, CS-series)

Reagents tested after 15 days at 2-8°C, or 7 days at RT (18-25°C) or Frozen ≤ -20°C

A405 values for UFH

	0.0	0.006	0.017	0.033	0.050	0.067	R^2	A405 (Free pNA)
Freshly restored	1.327	1.160	0.917	0.583	0.353	0.229	0.998	0.070
15 days at 2-8°C	1.326	1.151	0.902	0.564	0.341	0.224	0.998	0.071
7 days at RT (18-25°C)	1.294	1.129	0.885	0.558	0.337	0.219	0.998	0.069
Frozen ≤-20°C	1.310	1.141	0.896	0.567	0.342	0.222	0.998	0.068

Specifications: $R^2 \geq 0.98$; $\Delta A405(0\text{-}0.067) \geq 0.5$; Δ A405(0IU/mL) ≤ 10% between fresh and stored; A405(Free pNA) ≤ 0.30

Comments :

☒ **PASSED IN COMPLIANCE**

Date: 2023-07-05 **QC Manager:** S. LECOURT