

A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description: BIOPHEN HEPARIN (AT+)

Product Code: 221007

Lot No.: FB054118

Expiration date: 2024-09-14

Components	Quantity	Lot	Expiration Date
R1 : SXa-11 substrate	2 vials	FB0541HO18	2024-09-14
R2 : Bovine Fxa	2 vials	FB0541HP18	2024-10-05
R3 : Human AT	2 vials	FB0541HQ18	2024-09-20

Analytical Data	Specification	Result
SUPERIMPOSITION REACTIVITY, LINEARITY, ACCURACY ON STAR	• For a same A405 (UFH/LMWH): MV = TV ±0.05 IU/ml for conc. ≤ 0.50 IU/ml MV = TV ±0.10 IU/ml for conc. > 0.50 IU/ml • R²≥ 0.98	PASS
DETECTION THRESHOLD	≤ 0.05 IU/mL	< 0.01 IU/mL

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval: 2022-05-31 Quality Control Manager: S.LECOURT

F820-11-BI-1007-v7