



A Company of Sysmex Group



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN® AT anti-(h)-Xa LRT

**Product Code :** 221123

**Lot No. :** FC2317H7

**Expiration date :** 2026-05-01

Components	Quantity	Lot	Expiration Date
R1 : Human FXa	3 vials	FC2317FOH7	2026-05-01
R2 : FXa substrate	3 vials	FC2317FPH7	2026-05-01

Analytical Data	Specification	Result
Calibration curve : reactivity, slope, linearity and accuracy	Delta A405(100-50%) $\geq 0.25$ A405(100%) = $1.00 \pm 0.25$ $R^2 \geq 0.98$ Measured values for controls in acceptance ranges	0.38 1.12 > 0.99 PASS
DETECTION THRESHOLD	$\leq 10\%$	<3%

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

**Quality Control Approval**

Date of Approval :

14 DEC. 2023

S. LECOURT

Quality Control Manager :