

A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS

Product Description:

BIOPHEN HEPARIN CALIBRATOR

Product Code:

222001

Lot No.:

FD0550JH

Expiration date:

2026-09-08

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FD0550BJJH	2026-09-08
CAL 2	4 vials	FD0550BKJH	2026-09-08
CAL 3	4 vials	FD0550BLJH	2026-09-08
CAL 4	4 vials	FD0550BMJH	2026-09-08
CAL 5	4 vials	FD0550BNJH	2026-09-08

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 0.05 IU/mI CAL 2 : 0.30 -0.50 IU/mI CAL 3 : 0.70 -0.90 IU/mI CAL 4 : 1.10 -1.30 IU/mI CAL 5 : 1.45 -1.75 IU/mI	0.00 IU/mI 0.35 IU/mI 0.76 IU/mI 1.15 IU/mI 1.50 IU/mI
Linearity and accuracy of calibration with values assigned	$\label{eq:R2} R^2 \geq 0.98$ Measured values for controls in acceptance ranges	0.998 PASS

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

Date of Approval:

Quality Control Approval

Quality Control Manager:

09 AVR. 2024

S. LECOURT