



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. : FF0820V2 / FF0863
Expiration date : 2028-09-16

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FF0820BJV2 / FF0863	2028-09-16
CAL 2	4 vials	FF0820BKV2 / FF0863	2028-09-16
CAL 3	4 vials	FF0820BLV2 / FF0863	2028-09-16
CAL 4	4 vials	FF0820BMV2 / FF0863	2028-09-16
CAL 5	4 vials	FF0820BNV2 / FF0863	2028-09-16

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 0.05 IU/ml CAL 2 : 0.30 -0.50 IU/ml CAL 3 : 0.70 -0.90 IU/ml CAL 4 : 1.10 -1.30 IU/ml CAL 5 : 1.45 -1.75 IU/ml	0.00 IU/ml 0.39 IU/ml 0.80 IU/ml 1.20 IU/ml 1.59 IU/ml
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	PASS 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 :

21 AVR, 2026

S.MONEUS