

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.:

FB00081D

Expiration date:

2024-07-27

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FB0008BJ1D	2024-07-27
CAL 2	4 vials	FB0008BK1D	2024-07-27
CAL 3	4 vials	FB0008BL1D	2024-07-27
CAL 4	4 vials	FB0008BM1D	2024-07-27
CAL 5	4 vials	FB0008BN1D	2024-07-27

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 0.36 0.78 1.14 1.50
Linearity and accuracy of calibration with values assigned	$\label{eq:R2} R^2 \geq 0.98$ Measured values for controls in acceptance ranges	PASS

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

Date of Approval: 2022-03-29

**Quality Control Manager:** 

**S.LECOURT**