



A Company of Sysmex Group



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

CERTIFICATE OF ANALYSIS	
Product Description :	BIOPHEN ORGARAN CALIBRATOR
Product Code :	222201
Lot No. :	F1801535
Expiration date :	2021-05-15

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	F181301535	2021-05-15
CAL 2	4 vials	F181301535	2021-05-15
CAL 3	4 vials	F181301535	2021-05-15
CAL 4	4 vials	F181301535	2021-05-15
CAL 5	4 vials	F181301535	2021-05-15

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 0.05 U/ml CAL 2 : 0.30 -0.50 U/ml CAL 3 : 0.70 -0.90 U/ml CAL 4 : 1.10 -1.30 U/ml CAL 5 : 1.45 -1.75 U/ml	0.00 U/mL 0.41 U/mL 0.83 U/mL 1.21 U/mL 1.60 U/mL
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	1.00 Measured values for controls in acceptance ranges

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

Date of Approval : 2019-01-10

Quality Control Manager : S.LECOURT

**BIOPHEN ORGARAN® CALIBRATOR**Calibration plasmas for the assay of Sodium Danaparoid (Orgaran®) with anti-Xa methods /
Gamme de plasmas humains, à titre défini en Danaparoiide de Sodium (Orgaran®) pour l'étalonnage des dosages par méthode anti-Xa**REF** 222201

For in vitro diagnostic use only / Pour diagnostic in vitro exclusivement

LOT F1801535

2021-05-15

**Sodium Danaparoid (Orgaran®) Concentration [C] in the calibrators /
Concentration [C] en Danaparoiide de Sodium (Orgaran®) dans les calibrateurs**

<u>Calibrator / Calibreur 1</u>	LOT : F181301535
[C] :	0.00 U/mL
<u>Calibrator / Calibreur 2</u>	LOT : F181301535
[C] :	0.41 U/mL
<u>Calibrator / Calibreur 3</u>	LOT : F181301535
[C] :	0.83 U/mL
<u>Calibrator / Calibreur 4</u>	LOT : F181301535
[C] :	1.21 U/mL
<u>Calibrator / Calibreur 5</u>	LOT : F181301535
[C] :	1.60 U/mL

Standardization / Standardisation : **N/A**

Approved Date / Date d'Approbation : 2019-01-14

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT

