



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

## CERTIFICATE OF ANALYSIS

**Product Description :** BIOPHEN ARIXTRA CALIBRATOR  
**Product Code :** 222501  
**Lot No. :** F1800272  
**Expiration date :** 2020-08-22

Components	Quantity	Lot	Expiration Date
CAL 1	3 vials	F181200272	2020-08-22
CAL 2	3 vials	F181200272	2020-08-22
CAL 3	3 vials	F181200272	2020-08-22
CAL 4	3 vials	F181200272	2020-08-22

Analytical Data	Specification	Result
Concentration	CAL 1 : $\leq 0.05 \mu\text{g/ml}$ CAL 2 : $0.40 - 0.60 \mu\text{g/ml}$ CAL 3 : $0.90 - 1.10 \mu\text{g/ml}$ CAL 4 : $1.35 - 1.60 \mu\text{g/ml}$	0 $\mu\text{g/mL}$ 0,51 $\mu\text{g/mL}$ 0,98 $\mu\text{g/mL}$ 1,45 $\mu\text{g/mL}$
Linearity and accuracy of calibration with values assigned	$R^2 \geq 0.98$ Measured values for controls in acceptance ranges	$R^2 = 0.99$ controls are in compliance

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

Date of Approval : 2018-03-23

Quality Control Manager :

M. PEYRAFITTE



### BIOPHEN ARIXTRA® CALIBRATOR

Calibration plasmas for the assay of Arixtra® with anti-Xa methods /

*Gamme de plasmas humains, à titre défini en Arixtra® pour l'étalonnage des dosages d'Arixtra® par méthode anti-Xa*

**REF** 222501

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

**LOT** F1800272

2020-08-22

**Arixtra® Concentration [C] in the calibrators /  
Concentration [C] en Arixtra® dans les calibrateurs**

<b><u>Calibrator / Calibreur 1</u></b>	<b>LOT : F181200272</b>
[C] :	<b>0 µg/mL</b>
<b><u>Calibrator / Calibreur 2</u></b>	<b>LOT : F181200272</b>
[C] :	<b>0.51 µg/mL</b>
<b><u>Calibrator / Calibreur 3</u></b>	<b>LOT : F181200272</b>
[C] :	<b>0.98 µg/mL</b>
<b><u>Calibrator / Calibreur 4</u></b>	<b>LOT : F181200272</b>
[C] :	<b>1.45 µg/mL</b>

Standardization / *Standardisation* : **NIA**

Approved Date / *Date d'Approbation* : 2018-03-23

Quality Control Manager / *Responsable Contrôle Qualité* : Marie PEYRAFITTE