

ANALYSIS CERTIFICATE

BIOPHEN ARIXTRA CALIBRATOR - #222501

Lot : F1600278

QC release :

08/04/2016

Expiration date : 2018-08-28

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
CAL1 : Calibrator 1	3 vials	30	F161100278	F161100278	2018-08-28
CAL2 : Calibrator 2	3 vials	30	F161100278	F161100278	2018-08-28
CAL3 : Calibrator 3	3 vials	30	F161100278	F161100278	2018-08-28
CAL4 : Calibrator 4	3 vials	30	F161100278	F161100278	2018-08-28

205

ANALYSIS CERTIFICATE

BIOPHEN ARIXTRA CALIBRATOR - #222501

Lot : F1600278

QC release : 08/04/2016

Expiration date : 2018-08-28

Analytical data	Specifications															
<p>5. Calibration curve</p> <p style="text-align: center;"><input checked="" type="checkbox"/> STAR <input type="checkbox"/> ACL</p> <p style="text-align: center;">BIOPHEN Heparin Lot 50205 / 2016-07</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;"></th> <th style="width: 15%;">µg/ml</th> <th style="width: 15%;">A₄₀₅</th> </tr> </thead> <tbody> <tr> <td>Cal 1</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,657</td> </tr> <tr> <td>Cal 2</td> <td style="text-align: center;">0,50</td> <td style="text-align: center;">1,080</td> </tr> <tr> <td>Cal 3</td> <td style="text-align: center;">1,00</td> <td style="text-align: center;">0,715</td> </tr> <tr> <td>Cal 4</td> <td style="text-align: center;">1,47</td> <td style="text-align: center;">0,509</td> </tr> </tbody> </table>		µg/ml	A ₄₀₅	Cal 1	0	1,657	Cal 2	0,50	1,080	Cal 3	1,00	0,715	Cal 4	1,47	0,509	
	µg/ml	A ₄₀₅														
Cal 1	0	1,657														
Cal 2	0,50	1,080														
Cal 3	1,00	0,715														
Cal 4	1,47	0,509														

<p>6. Linearity</p> <p style="text-align: center;">r^2 0,998</p>	<p>$r^2 \geq 0.98$</p>
---	-----------------------------------

<p>7. Accuracy</p> <p style="text-align: center;"><input checked="" type="checkbox"/> STAR <input type="checkbox"/> ACL</p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">CONTROLS</th> <th style="width: 10%;">TV*</th> <th style="width: 10%;">MV*</th> </tr> </thead> <tbody> <tr> <td>C1 Lot 51606-1 / 2017-10 [0,36 - 0,56] µg/ml</td> <td style="text-align: center;">0,46</td> <td style="text-align: center;">0,51</td> </tr> <tr> <td>C2 Lot 51606-2 / 2017-10 [1,10 - 1,42] µg/ml</td> <td style="text-align: center;">1,26</td> <td style="text-align: center;">1,28</td> </tr> </tbody> </table> <p style="text-align: center; font-size: small;">*TV: Target Value *MV: Measured Value</p>	CONTROLS	TV*	MV*	C1 Lot 51606-1 / 2017-10 [0,36 - 0,56] µg/ml	0,46	0,51	C2 Lot 51606-2 / 2017-10 [1,10 - 1,42] µg/ml	1,26	1,28	<p>MV* within the acceptance range</p>
CONTROLS	TV*	MV*								
C1 Lot 51606-1 / 2017-10 [0,36 - 0,56] µg/ml	0,46	0,51								
C2 Lot 51606-2 / 2017-10 [1,10 - 1,42] µg/ml	1,26	1,28								

<p>Comments :</p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>
--------------------------	--

Date : 08/04/2016

QC Manager :

S. LECOURT

ANALYSIS CERTIFICATE

BIOPHEN ARIXTRA CALIBRATOR - #222501

Lot : F1600278

QC Release :

08/04/2016

Expiration date : 2018-08-28

Analytical data				Specifications
1. <u>Within lot reproducibility (N ≥ 10)</u>				
Mean OD				
N= 15	CAL1:	0,848	CV: 0,9 %	CV (OD) ≤ 2%
N= 15	CAL2:	0532	CV: 1,2 %	CV (OD) ≤ 2%
N= 15	CAL3:	0,360	CV: 1,9 %	CV (OD) ≤ 2%
N= 15	CAL4:	0,263	CV: 1,5 %	CV (OD) ≤ 2%

2. <u>Concentration [C] and Standard Deviation (SD)</u>				
Internal Reference standard lot:		50403 / 2017-07		
Controls	N series	[C] µg/mL	SD	
CAL1	10	0	0	
CAL2	10	0,50	0,022	
CAL3	10	1,00	0,031	
CAL4	10	1,47	0,063	

CAL1: ≤ 0.05 µg/ml

CAL2: 0.40-0.60 µg/mL

CAL3: 0.90-1.10 µg/mL

CAL4: 1.35-1.60 µg/mL

3. <u>Aspect</u>				
<input checked="" type="checkbox"/>	Slightly opalescent to clear			a) Slightly opalescent to clear
<input checked="" type="checkbox"/>	No coagulum			b) No coagulum
<input checked="" type="checkbox"/>	Stable solution			c) Stable solution

4. <u>Stability of reconstituted reagents</u>					
		Fresh	48h	7 days	
		/	RT	2-8°C	
CAL1	µg/mL	0	0	0,01	48 hours at RT: Δ [C] ≤ 0.05µg/ml for cal1 and cal2 Δ [C] ≤ 10% for cal3 and cal4
	Δ µg/ml	NA	0	0,01	
CAL2	µg/mL	0,55	0,53	0,53	7 days at 2-8°C: Δ [C] ≤ 0.05µg/ml for cal1 and cal2 Δ [C] ≤ 10% for cal3 and cal4
	Δ µg/ml	NA	0,02	0,02	
CAL3	µg/mL	1,03	1,01	1,01	Δ [C] ≤ 10% for cal3 and cal4
	Δ %	NA	1,9 %	1,9 %	
CAL4	µg/mL	1,47	1,46	1,44	Δ [C] ≤ 10% for cal3 and cal4
	Δ %	NA	0,7 %	2,0 %	

BIOPHEN ARIXTRA® CALIBRATOR
Référence 222501

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : F1600278 - Exp. : 2018-08-28

Concentration [C] en Arixtra® dans les calibrateurs

<u>Cal 1</u>	Lot : F161100278
	[C] : 0 µg/mL
<u>Cal 2</u>	Lot : F161100278
	[C] : 0,50 µg/mL
<u>Cal 3</u>	Lot : F161100278
	[C] : 1,00 µg/mL
<u>Cal 4</u>	Lot : F161100278
	[C] : 1,47 µg/mL

BIOPHEN ARIXTRA® CALIBRATOR
222501

For *in vitro* diagnostic use only

ENGLISH

Lot : F1600278 - Exp. : 2018-08-28

Arixtra® concentration [C] in the calibrators

<u>Cal 1</u>	Lot : F161100278
	[C] : 0 µg/mL
<u>Cal 2</u>	Lot : F161100278
	[C] : 0,50 µg/mL
<u>Cal 3</u>	Lot : F161100278
	[C] : 1,00 µg/mL
<u>Cal 4</u>	Lot : F161100278
	[C] : 1,47 µg/mL

BIOPHEN ARIXTRA® CALIBRATOR
Référence 222501

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : F1600278 - Exp. : 2018-08-28

Concentration [C] en Arixtra® dans les calibrateurs

<u>Cal 1</u>	Lot : F161100278
	[C] : 0 µg/mL
<u>Cal 2</u>	Lot : F161100278
	[C] : 0,50 µg/mL
<u>Cal 3</u>	Lot : F161100278
	[C] : 1,00 µg/mL
<u>Cal 4</u>	Lot : F161100278
	[C] : 1,47 µg/mL

BIOPHEN Arixtra® CALIBRATOR
222501

For *in vitro* diagnostic use only

ENGLISH

Lot : F1600278 - Exp. : 2018-08-28

Arixtra® concentration [C] in the calibrators

<u>Cal 1</u>	Lot : F161100278
	[C] : 0 µg/mL
<u>Cal 2</u>	Lot : F161100278
	[C] : 0,50 µg/mL
<u>Cal 3</u>	Lot : F161100278
	[C] : 1,00 µg/mL
<u>Cal 4</u>	Lot : F161100278
	[C] : 1,47 µg/mL

