

ANALYSIS CERTIFICATE

BIOPHEN ARIXTRA CONTROL PLASMA - #224001 Lot : **F1701422**
F1701423
QC release : 2018-01-16 Expiration date : **2020-05-11**

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F171101422 F171201423	2020-05-11
C2 : Control 2	6 vials	30	F171101422 F171201423	2020-05-11

KVA

ANALYSIS CERTIFICATE

BIOPHEN ARIXTRA CONTROL PLASMA - #224001

Lot : F1701422
F1701423

QC release : 2018-01-16

Expiration date : 2020-05-11

Analytical data	Specifications								
1. <u>Within lot reproducibility</u> <div style="text-align: center;"><u>Mean OD</u></div> <table style="width: 100%; border: none;"> <tr> <td style="width: 20%;">N= 25</td> <td style="width: 20%;">C1: 0,471</td> <td style="width: 20%;">CV: 0,9 %</td> <td style="width: 40%;"></td> </tr> <tr> <td>N= 25</td> <td>C2: 0,211</td> <td>CV: 1,8 %</td> <td></td> </tr> </table>	N= 25	C1: 0,471	CV: 0,9 %		N= 25	C2: 0,211	CV: 1,8 %		CV(OD) ≤ 2% CV(OD) ≤ 2%
N= 25	C1: 0,471	CV: 0,9 %							
N= 25	C2: 0,211	CV: 1,8 %							

2. <u>Concentration [C], Standard deviation (SD) and acceptance range</u> Internal Reference standard lot: 50403																
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Controls</th> <th>N series</th> <th>[C] µg/mL</th> <th>SD</th> <th>Acceptance range (µg/mL)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">C1</td> <td style="text-align: center;">13</td> <td style="text-align: center;">0,43</td> <td style="text-align: center;">0,02</td> <td style="text-align: center;">0,33-0,53</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">13</td> <td style="text-align: center;">1,21</td> <td style="text-align: center;">0,04</td> <td style="text-align: center;">1,05-1,37</td> </tr> </tbody> </table>	Controls	N series	[C] µg/mL	SD	Acceptance range (µg/mL)	C1	13	0,43	0,02	0,33-0,53	C2	13	1,21	0,04	1,05-1,37	C1: 0.30 to 0.50 µg/mL C2: 1.05 to 1.35 µg/mL
Controls	N series	[C] µg/mL	SD	Acceptance range (µg/mL)												
C1	13	0,43	0,02	0,33-0,53												
C2	13	1,21	0,04	1,05-1,37												

3. <u>Aspect</u> <input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable solution	Slightly opalescent to clear No coagulum Stable solution
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4. <u>Stability of reconstituted reagents</u> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th rowspan="2"></th> <th rowspan="2">Temp.</th> <th colspan="2">C1</th> <th colspan="2">C2</th> </tr> <tr> <th>µg/mL</th> <th>Δ [C]</th> <th>µg/mL</th> <th>Δ[C]%</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td>/</td> <td>0,44</td> <td>NA</td> <td>1,22</td> <td>NA</td> </tr> <tr> <td>48h</td> <td>RT</td> <td>0,46</td> <td>0,02</td> <td>1,25</td> <td>2,5</td> </tr> <tr> <td>7 days</td> <td>2-8°C</td> <td>0,44</td> <td>0</td> <td>1,21</td> <td>0,8</td> </tr> </tbody> </table>		Temp.	C1		C2		µg/mL	Δ [C]	µg/mL	Δ[C]%	Fresh	/	0,44	NA	1,22	NA	48h	RT	0,46	0,02	1,25	2,5	7 days	2-8°C	0,44	0	1,21	0,8	<u>48h at RT (18-25°C) and</u> <u>7 days at 2-8°C</u> C1 : Δ [C] ≤ 0.05µg/ml C2 : Δ [C] ≤ 10%
			Temp.	C1		C2																							
	µg/mL	Δ [C]		µg/mL	Δ[C]%																								
Fresh	/	0,44	NA	1,22	NA																								
48h	RT	0,46	0,02	1,25	2,5																								
7 days	2-8°C	0,44	0	1,21	0,8																								

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2018-01-16

QC Manager :

S.LECOURT

p/o Keshia VALASTRO



BIOPHEN® ARIXTRA® CONTROL

Control plasmas for the quality control of Arixtra® measurements with anti-Xa method /

Plasmas de contrôle surchargés et titrés pour le contrôle de qualité des dosages de l'Arixtra® par méthode chromogénique anti-Xa

REF 224001

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

LOT

F1701423



2020-05-11

Arixtra® Concentration [C] in the controls / *Concentration [C] en Arixtra® dans les contrôles*

Control / Contrôle C1	LOT : F171201423
Target value / <i>Valeur cible</i> :	0.43 µg/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[0.33 - 0.53] µg/mL

Control / Contrôle C2	LOT : F171201423
Target value / <i>Valeur cible</i> :	1.21 µg/mL
Acceptance range / <i>Intervalle d'acceptation</i> :	[1.05 - 1.37] µg/mL

Standardization / *Standardisation* : N/A

Approved Date / *Date d'Approbation* : 2018-01-16

Quality Control Manager / *Responsable Contrôle Qualité* : S.LECOURT

p/o Keshia VALATOSCO
[Signature]