

ANALYSIS CERTIFICATE

BIOPHEN ARIXTRA CONTROL PLASMA - #224001

Lot : F1600528

QC release : 05.07.2016

Expiration date : 2018-11-24

Components	Volume	Exp. (months)	Lot #	Exp. date
C1 : Control 1	6 vials	30	F161100528	2018-11-24
C2 : Control 2	6 vials	30	F161100528	2018-11-24

SPS

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Lot : F1600528

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Analytical data	Specifications								
1. <u>Within lot reproducibility</u> <div style="text-align: center;">Mean OD</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N= 25</td> <td style="width: 20%;">C1: 0,434</td> <td style="width: 15%;">CV: 1,3 %</td> <td style="width: 50%;"></td> </tr> <tr> <td>N= 25</td> <td>C2: 0,203</td> <td>CV: 1,9 %</td> <td></td> </tr> </table>	N= 25	C1: 0,434	CV: 1,3 %		N= 25	C2: 0,203	CV: 1,9 %		CV(OD) ≤ 2% CV(OD) ≤ 2%
N= 25	C1: 0,434	CV: 1,3 %							
N= 25	C2: 0,203	CV: 1,9 %							

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;">11</td> <td style="text-align: center;">0,46</td> <td style="text-align: center;">0,015</td> <td style="text-align: center;">0,36 - 0,56</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">11</td> <td style="text-align: center;">1,24</td> <td style="text-align: center;">0,038</td> <td style="text-align: center;">1,08 - 1,40</td> </tr> </tbody> </table>	Controls	N series	[C] µg/mL	SD	Acceptance range (µg/mL)	C1	11	0,46	0,015	0,36 - 0,56	C2	11	1,24	0,038	1,08 - 1,40	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	11	0,46	0,015	0,36 - 0,56												
C2	11	1,24	0,038	1,08 - 1,40												

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; margin-left: auto; margin-right: auto;"> <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 style="text-align: center;">Fresh</td> <td style="text-align: center;">/</td> <td style="text-align: center;">0,49</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">1,28</td> <td style="text-align: center;">NA</td> </tr> <tr> <td style="text-align: center;">48h</td> <td style="text-align: center;">RT</td> <td style="text-align: center;">0,49</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,25</td> <td style="text-align: center;">2,3</td> </tr> <tr> <td style="text-align: center;">7 days</td> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">0,49</td> <td style="text-align: center;">0</td> <td style="text-align: center;">1,26</td> <td style="text-align: center;">1,6</td> </tr> </tbody> </table>		Temp.	C1		C2		µg/mL	Δ [C]	µg/mL	Δ[C]%	Fresh	/	0,49	NA	1,28	NA	48h	RT	0,49	0	1,25	2,3	7 days	2-8°C	0,49	0	1,26	1,6	<u>48h at RT (18-25°C) and 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	/	0,49	NA	1,28	NA																								
48h	RT	0,49	0	1,25	2,3																								
7 days	2-8°C	0,49	0	1,26	1,6																								

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 05.07.2016

QC Manager :

S. LECOURT





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 homogène anti-Xa

REF 224001

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

LOT F1600528 2018-11-24

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

Control / Contrôle C1	LOT : F161100528
Target value / Valeur cible :	0.46 µg/mL
Acceptance range / Intervalle d'acceptation :	[0.36 – 0.56] µg/mL

Control / Contrôle C2	LOT : F161100528
Target value / Valeur cible :	1.24 µg/mL
Acceptance range / Intervalle d'acceptation :	[1.08 – 1.40] µg/mL

Standardization / Standardisation : NA

Approved Date / Date d'Approbation : 2017-08-31

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT