

ANALYSIS CERTIFICATE

BIOPHEN ARIXTRA CONTROL PLASMA - #224001

Lot : 54702

QC release : 07/12/2015

Expiration date : 2018.05.31

Components	Volume	Exp. (months)	Int. Ref.	Lot #	Exp. date
C1 : Control 1	6 vials	30	151117B	54702-1	2018-05
C2 : Control 2	6 vials	30	151117C	54702-2	2018-05

MS

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Analytical data	Specifications								
1. <u>Within lot reproducibility (N ≥ 10)</u> <div style="text-align: center;">Mean OD</div> <table style="width: 100%; border: none;"> <tr> <td style="width: 15%;">N= 20</td> <td style="width: 35%;">C1: 0,455</td> <td style="width: 15%;">CV: 0,7 %</td> <td style="width: 35%;"></td> </tr> <tr> <td>N= 20</td> <td>C2: 0,207</td> <td>CV: 1,3 %</td> <td></td> </tr> </table>	N= 20	C1: 0,455	CV: 0,7 %		N= 20	C2: 0,207	CV: 1,3 %		OD : CV ≤ 2% OD : CV ≤ 2%
N= 20	C1: 0,455	CV: 0,7 %							
N= 20	C2: 0,207	CV: 1,3 %							

2. <u>Concentration [C], Standard deviation (SD) and acceptance range</u> Internal Reference standard lot: 50403 (2017-07)	Target value: C1: 0.30 to 0.50 µg/mL C2: 1.05 to 1.35 µg/mL															
<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;">10</td> <td style="text-align: center;">0,42</td> <td style="text-align: center;">0,010</td> <td style="text-align: center;">0,32-0,52</td> </tr> <tr> <td style="text-align: center;">C2</td> <td style="text-align: center;">10</td> <td style="text-align: center;">1,20</td> <td style="text-align: center;">0,022</td> <td style="text-align: center;">1,04-1,36</td> </tr> </tbody> </table>		Controls	N series	[C] µg/mL	SD	Acceptance range (µg/mL)	C1	10	0,42	0,010	0,32-0,52	C2	10	1,20	0,022	1,04-1,36
Controls		N series	[C] µg/mL	SD	Acceptance range (µg/mL)											
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3. <u>Aspect</u> <input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable solution	a) Slightly opalescent to clear b) No coagulum c) 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 µg/ml</th> <th>µg/mL</th> <th>Δ %</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Fresh</td> <td style="text-align: center;">/</td> <td style="text-align: center;">0,43</td> <td style="text-align: center;">NA</td> <td style="text-align: center;">1,18</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;">0,41</td> <td style="text-align: center;">0,02</td> <td style="text-align: center;">1,21</td> <td style="text-align: center;">2,5</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;">0,42</td> <td style="text-align: center;">0,01</td> <td style="text-align: center;">1,20</td> <td style="text-align: center;">1,7</td> </tr> </tbody> </table>		Temp.	C1		C2		µg/mL	Δ µg/ml	µg/mL	Δ %	Fresh	/	0,43	NA	1,18	NA	48h	RT	0,41	0,02	1,21	2,5	7 days	2-8°C	0,42	0,01	1,20	1,7	48 hours at RT: Δ [C] ≤ 0.05µg/ml for C1 Δ [C] ≤ 10% for C2 7 days at 2-8°C: Δ [C] ≤ 0.05µg/ml for C1 Δ [C] ≤ 10% for C2
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Comments : <div style="height: 40px;"></div>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 07/12/2015

QC Manager :

S.LECOURT



BIOPHEN ARIXTRA® CONTROL PLASMA
Référence 224001

Pour diagnostic *in vitro* exclusivement

FRANÇAIS

Lot : 54702 - Exp. : 2018.05.31

C1 (Contrôle 1) Lot : 54702-1
[C] : 0.42 µg/mL
Intervalle de confiance : 0.32 – 0.52 µg/mL

C2 (Contrôle 2) Lot : 54702-2
[C] : 1.20 µg/mL
Intervalle de confiance : 1.04 – 1.36 µg/mL

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*Control
07.12.13*

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