

ANALYSIS CERTIFICATE

FIX deficient plasma - # DP050A/DP050K

Lot : 53002-1

QC release: 11/08/2015

Expiration date : 2018-01

DP050A : 1 mL

DP050K : 6 x 1 mL

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
FIX deficient plasma	Vial of 1 ml	30	150721A	53002-1	2018-01

303

ANALYSIS CERTIFICATE

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Lot : 53002-1

QC release:

11/08/2015

Expiration date : 2018-01

Analytical data	Specifications
1. <u>Within lot reproducibility (N ≥ 5)</u>	
N= 15 PT 10,0 sec CV%: 1,3	< 15 Sec (CV ≤ 3%)
N= 5 aPTT 152,9 sec	> 100 Sec

2. <u>Concentration [C]</u>	
FIX (Elisa) <1 %	< 1%

3. <u>Aspect</u>	
a) : Slightly opalescent to clear	a) Slightly opalescent to clear
b) : No coagulum	b) No coagulum
c) : Stable solution	c) Stable solution

4. <u>FIX Clotting assay</u>															
Instrument: MC10															
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th style="width: 10%;">IX %</th> <th style="width: 10%;">100</th> <th style="width: 10%;">50</th> <th style="width: 10%;">25</th> <th style="width: 10%;">12.5</th> <th style="width: 10%;">6.25</th> <th style="width: 10%;">0</th> </tr> </thead> <tbody> <tr> <td>CT (Sec)</td> <td style="text-align: center;">52,1</td> <td style="text-align: center;">59,6</td> <td style="text-align: center;">67,4</td> <td style="text-align: center;">76,5</td> <td style="text-align: center;">86,1</td> <td style="text-align: center;">166,6</td> </tr> </tbody> </table>	IX %	100	50	25	12.5	6.25	0	CT (Sec)	52,1	59,6	67,4	76,5	86,1	166,6	Δ CT (0-100%) ≥ 40 sec CT (100%) < 80sec
IX %	100	50	25	12.5	6.25	0									
CT (Sec)	52,1	59,6	67,4	76,5	86,1	166,6									

5. <u>Stability of reconstituted reagent</u>																				
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th rowspan="2"></th> <th style="width: 10%;">Fresh</th> <th style="width: 10%;">24h</th> <th style="width: 10%;">8h</th> </tr> <tr> <th></th> <th style="text-align: center;">2-8°C</th> <th style="text-align: center;">RT</th> </tr> </thead> <tbody> <tr> <td>PT (sec)</td> <td style="text-align: center;">11,4</td> <td style="text-align: center;">12,1</td> <td style="text-align: center;">11,8</td> </tr> <tr> <td>aPTT (sec)</td> <td style="text-align: center;">126,2</td> <td style="text-align: center;">129,4</td> <td style="text-align: center;">128,5</td> </tr> <tr> <td>CT (C%) (sec)</td> <td style="text-align: center;">57,2</td> <td style="text-align: center;">56,9</td> <td style="text-align: center;">54,4</td> </tr> </tbody> </table>		Fresh	24h	8h		2-8°C	RT	PT (sec)	11,4	12,1	11,8	aPTT (sec)	126,2	129,4	128,5	CT (C%) (sec)	57,2	56,9	54,4	Δ ≤ 1 sec Δ ≤ 5 sec Δ ≤ 3 sec
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		2-8°C	RT																	
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Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 11/08/2015 **QC Manager :** S.LECOURT

