

## 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*

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**FIX deficient plasma - # DP050A/DP050K**

**Lot : 53002-1**

**QC release:**

**11/08/2015**

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

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

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

<b>4. <u>FIX Clotting assay</u></b>															
Instrument:                      MC10															
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td style="width: 10%;">IX %</td> <td style="width: 15%;">100</td> <td style="width: 15%;">50</td> <td style="width: 15%;">25</td> <td style="width: 15%;">12.5</td> <td style="width: 15%;">6.25</td> <td style="width: 15%;">0</td> </tr> <tr> <td>CT (Sec)</td> <td style="text-align: center;"><b>52,1</b></td> <td style="text-align: center;"><b>59,6</b></td> <td style="text-align: center;"><b>67,4</b></td> <td style="text-align: center;"><b>76,5</b></td> <td style="text-align: center;"><b>86,1</b></td> <td style="text-align: center;"><b>166,6</b></td> </tr> </table>	IX %	100	50	25	12.5	6.25	0	CT (Sec)	<b>52,1</b>	<b>59,6</b>	<b>67,4</b>	<b>76,5</b>	<b>86,1</b>	<b>166,6</b>	Δ CT (0-100%) ≥ 40 sec CT (100%) < 80sec
IX %	100	50	25	12.5	6.25	0									
CT (Sec)	<b>52,1</b>	<b>59,6</b>	<b>67,4</b>	<b>76,5</b>	<b>86,1</b>	<b>166,6</b>									

<b>5. <u>Stability of reconstituted reagent</u></b>																					
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td></td> <td style="text-align: center;">Fresh</td> <td style="text-align: center;">24h</td> <td style="text-align: center;">8h</td> </tr> <tr> <td></td> <td></td> <td style="text-align: center;">2-8°C</td> <td style="text-align: center;">RT</td> </tr> <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> </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
	Fresh	24h	8h																		
		2-8°C	RT																		
PT (sec)	11,4	12,1	11,8																		
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Comments :	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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**Date :** 11/08/2015                      **QC Manager :** S.LECOURT

