

## ANALYSIS CERTIFICATE

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

**Lot : F1600380**

**QC release: 04/05/2016**

**Expiration date : 2018-10-02**

**DP050A : 1 mL**

**DP050K : 6 x 1 mL**

<b>Components</b>	<b>Qty</b>	<b>Exp. (months)</b>	<b>Int. Ref.</b>	<b>Lot #</b>	<b>Exp. date</b>
FIX deficient plasma	Vial of 1 ml	30	F161100380	F161100380	2018-10-02

*SJB*

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**Lot : F1600380**

**QC release:**

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Analytical data	Specifications
<b>1. <u>Within lot reproducibility (N ≥ 5)</u></b>  N=            10                    CV%:    1,7	CV ≤ 3%

<b>2. <u>Concentration [C]</u></b>  Factor IX :                    <1 % Factor V :                      100 %	< 1% > 50%
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<b>3. <u>Aspect</u></b>  a) :            Slightly opalescent to clear  b) :            No coagulum  c) :            Stable solution	a) Slightly opalescent to clear b) No coagulum c) Stable solution
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<b>4. <u>FIX Clotting assay</u></b>  <div style="text-align: right; margin-right: 20px;">Instrument:            MC10</div> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <tr> <td style="width: 15%;">IX %</td> <td style="width: 12.5%;">100</td> <td style="width: 12.5%;">50</td> <td style="width: 12.5%;">25</td> <td style="width: 12.5%;">12.5</td> <td style="width: 12.5%;">6.25</td> <td style="width: 12.5%;">0</td> </tr> <tr> <td>CT (Sec)</td> <td>49,9</td> <td>56,1</td> <td>62,8</td> <td>71,5</td> <td>80,5</td> <td>160,2</td> </tr> </table>	IX %	100	50	25	12.5	6.25	0	CT (Sec)	49,9	56,1	62,8	71,5	80,5	160,2	Δ CT (0-100%) ≥ 40 sec CT (100%) < 80sec
IX %	100	50	25	12.5	6.25	0									
CT (Sec)	49,9	56,1	62,8	71,5	80,5	160,2									

<b>5. <u>Stability of reconstituted reagent</u></b>  <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <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;">10,8</td> <td style="text-align: center;">11,1</td> <td style="text-align: center;">11,3</td> </tr> <tr> <td>aPTT (sec)</td> <td style="text-align: center;">149,4</td> <td style="text-align: center;">151,1</td> <td style="text-align: center;">149,2</td> </tr> <tr> <td>CT (C%) (sec)</td> <td style="text-align: center;">51,3</td> <td style="text-align: center;">52,7</td> <td style="text-align: center;">52,7</td> </tr> </table>		Fresh	24h	8h			2-8°C	RT	PT (sec)	10,8	11,1	11,3	aPTT (sec)	149,4	151,1	149,2	CT (C%) (sec)	51,3	52,7	52,7	Δ ≤ 1 sec Δ ≤ 5 sec Δ ≤ 3 sec
	Fresh	24h	8h																		
		2-8°C	RT																		
PT (sec)	10,8	11,1	11,3																		
aPTT (sec)	149,4	151,1	149,2																		
CT (C%) (sec)	51,3	52,7	52,7																		

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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**Date :**    04/05/2016

**QC Manager :**

**S. LECOURT**