

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

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

SJB

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Lot : F1600380

QC release:

04.05.2016

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

2. <u>Concentration [C]</u> Factor IX : <1 % Factor V : 100 %	< 1% > 50%
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3. <u>Aspect</u> 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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4. <u>FIX Clotting assay</u> <div style="text-align: right; margin-right: 50px;">Instrument: MC10</div> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="padding: 2px;">IX %</td> <td style="padding: 2px;">100</td> <td style="padding: 2px;">50</td> <td style="padding: 2px;">25</td> <td style="padding: 2px;">12,5</td> <td style="padding: 2px;">6,25</td> <td style="padding: 2px;">0</td> </tr> <tr> <td style="padding: 2px;">CT (Sec)</td> <td style="padding: 2px;">49,9</td> <td style="padding: 2px;">56,1</td> <td style="padding: 2px;">62,8</td> <td style="padding: 2px;">71,5</td> <td style="padding: 2px;">80,5</td> <td style="padding: 2px;">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									

5. <u>Stability of reconstituted reagent</u> <table border="1" style="margin-left: auto; margin-right: 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 style="padding: 2px;">PT (sec)</td> <td style="padding: 2px;">10,8</td> <td style="padding: 2px;">11,1</td> <td style="padding: 2px;">11,3</td> </tr> <tr> <td style="padding: 2px;">aPTT (sec)</td> <td style="padding: 2px;">149,4</td> <td style="padding: 2px;">151,1</td> <td style="padding: 2px;">149,2</td> </tr> <tr> <td style="padding: 2px;">CT (C%) (sec)</td> <td style="padding: 2px;">51,3</td> <td style="padding: 2px;">52,7</td> <td style="padding: 2px;">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