

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

ANALYSIS CERTIFICATE

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Lot : F1600380

QC release:

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Analytical data	Specifications																				
<p>1. <u>Within lot reproducibility (N ≥ 5)</u></p> <p>N= 10 CV%: 1,7</p>	CV ≤ 3%																				
<p>2. <u>Concentration [C]</u></p> <p>Factor IX : <1 %</p> <p>Factor V : 100 %</p>	<p>< 1%</p> <p>> 50%</p>																				
<p>3. <u>Aspect</u></p> <p>a) : Slightly opalescent to clear</p> <p>b) : No coagulum</p> <p>c) : Stable solution</p>	<p>a) Slightly opalescent to clear</p> <p>b) No coagulum</p> <p>c) Stable solution</p>																				
<p>4. <u>FIX Clotting assay</u></p> <p style="text-align: center;">Instrument: MC10</p> <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	<p>Δ CT (0-100%) ≥ 40 sec</p> <p>CT (100%) < 80sec</p>						
IX %	100	50	25	12,5	6,25	0															
CT (Sec)	49,9	56,1	62,8	71,5	80,5	160,2															
<p>5. <u>Stability of reconstituted reagent</u></p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td></td> <td style="padding: 2px;">Fresh</td> <td style="padding: 2px;">24h</td> <td style="padding: 2px;">8h</td> </tr> <tr> <td></td> <td></td> <td style="padding: 2px;">2-8°C</td> <td style="padding: 2px;">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	<p>Δ ≤ 1 sec</p> <p>Δ ≤ 5 sec</p> <p>Δ ≤ 3 sec</p>
	Fresh	24h	8h																		
		2-8°C	RT																		
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Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 04/05/2016

QC Manager :

S. LECOURT