

ANALYSIS CERTIFICATE

FVIII:C deficient plasma - # DP040A/DP040K

QC release: 2017-12-08

DP040A : 1 mL

DP040K : 6 x 1 mL

F1701353

Lot : F1701354

Expiration date : 2020-05-05

Components	Qty	Exp. (months)	LOT	Exp. date
FVIII:C deficient plasma	Vial of 1 ml	30	F171201353 F171201354	2020-05-05

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FVIII:C deficient plasma - # DP040A/DP040K

F1701353

Lot : F1701354

QC release: 2017-12-08

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Analytical data	Specifications																			
1. <u>Within lot reproducibility</u>																				
N= 10 CV%: 2,1%	CV ≤ 3%																			
2. <u>Concentration [C]</u>																				
Factor VIII:C : < 1 %	< 1%																			
Factor V : 89 %	> 50%																			
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>FVIII:C Clotting assay</u> <u>STAR</u>																				
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td>VIII:C %</td> <td>100</td> <td>50</td> <td>25</td> <td>12.5</td> <td>6.25</td> <td>0</td> </tr> <tr> <td>CT (Sec)</td> <td>55,1</td> <td>62</td> <td>69,9</td> <td>77,6</td> <td>85,9</td> <td>109,1</td> </tr> </table>	VIII:C %	100	50	25	12.5	6.25	0	CT (Sec)	55,1	62	69,9	77,6	85,9	109,1	Δ CT (0-100%) ≥ 40 sec CT (100%) < 75sec					
VIII:C %	100	50	25	12.5	6.25	0														
CT (Sec)	55,1	62	69,9	77,6	85,9	109,1														
5. <u>Stability of reconstituted reagent</u>																				
<table border="1" style="margin: auto; border-collapse: collapse;"> <tr> <td></td> <td rowspan="2" 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 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;">15,2</td> <td style="text-align: center;">14,6</td> <td style="text-align: center;">14,5</td> </tr> <tr> <td>aPTT (sec)</td> <td style="text-align: center;">88,5</td> <td style="text-align: center;">88,6</td> <td style="text-align: center;">87,5</td> </tr> <tr> <td>CT (C %) (sec)</td> <td style="text-align: center;">51,6</td> <td style="text-align: center;">51,3</td> <td style="text-align: center;">52,1</td> </tr> </table>		Fresh	24h	8h		2-8°C	RT	PT (sec)	15,2	14,6	14,5	aPTT (sec)	88,5	88,6	87,5	CT (C %) (sec)	51,6	51,3	52,1	Δ ≤ 1 sec Δ ≤ 3 sec Δ ≤ 3 sec
	Fresh		24h	8h																
		2-8°C	RT																	
PT (sec)	15,2	14,6	14,5																	
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Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-12-08 **QC Manager :** S.LECOURT