

ANALYSIS CERTIFICATE

FVIII:C deficient plasma - # DP040A/DP040K

Lot : 54602-1

QC release:

01/12/2015

Expiration date : 2018-05-31

DP040A : 1 mL

DP040K : 6 x 1 mL

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
FVIII:C deficient plasma	Vial of 1 ml	30	151113B	54602-1	2018-05-31

SAS

ANALYSIS CERTIFICATE

FVIII:C deficient plasma - # DP040A/DP040K

Lot : 54602-1

QC release:

01/12/2015

Expiration date : 2018-05-31

Analytical data	Specifications
1. <u>Within lot reproducibility (N ≥ 5)</u>	
N= 20 PT 15,9 (*) sec CV%: 1,0%	< 15 Sec (CV ≤ 3%) > 90 Sec
N= 5 aPTT 116,3 sec	

2. <u>Concentration [C]</u>	
FVIII:C <1 %	< 1%

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

4. <u>FVIII:C Clotting assay</u> <u>METHOD: 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>62,3</td> <td>71,5</td> <td>80,4</td> <td>90,0</td> <td>100,0</td> <td>148,6</td> </tr> </table>	VIII:C %	100	50	25	12,5	6,25	0	CT (Sec)	62,3	71,5	80,4	90,0	100,0	148,6	ΔCT (0-100%) ≥ 40 sec CT (100%) < 75sec
VIII:C %	100	50	25	12,5	6,25	0									
CT (Sec)	62,3	71,5	80,4	90,0	100,0	148,6									

5. <u>Stability of reconstituted reagent</u>																					
<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;">16,1</td> <td style="text-align: center;">16,2</td> <td style="text-align: center;">16,5</td> </tr> <tr> <td>aPTT (sec)</td> <td style="text-align: center;">128,1</td> <td style="text-align: center;">127,8</td> <td style="text-align: center;">127,6</td> </tr> <tr> <td>CT (C %) (sec)</td> <td style="text-align: center;">63,8</td> <td style="text-align: center;">64,4</td> <td style="text-align: center;">64,0</td> </tr> </table>		Fresh	24h	8h			2-8°C	RT	PT (sec)	16,1	16,2	16,5	aPTT (sec)	128,1	127,8	127,6	CT (C %) (sec)	63,8	64,4	64,0	Δ ≤ 1 sec Δ ≤ 3 sec Δ ≤ 3 sec
	Fresh	24h	8h																		
		2-8°C	RT																		
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Comments : (*) Accepted under waiver (NCI 1206)	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 01/12/2015 **QC Manager :** S. LECOURT

