

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 % Factor V : 89 %	< 1% > 50%																				
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																				
4. <u>FVIII:C Clotting assay</u> <u>STAR</u>																					
<table border="1" style="border-collapse: collapse; width: 100%;"> <tr> <td style="padding: 2px;">VIII:C %</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;">55,1</td> <td style="padding: 2px;">62</td> <td style="padding: 2px;">69,9</td> <td style="padding: 2px;">77,6</td> <td style="padding: 2px;">85,9</td> <td style="padding: 2px;">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="border-collapse: collapse; width: 100%;"> <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;">15,2</td> <td style="padding: 2px;">14,6</td> <td style="padding: 2px;">14,5</td> </tr> <tr> <td style="padding: 2px;">aPTT (sec)</td> <td style="padding: 2px;">88,5</td> <td style="padding: 2px;">88,6</td> <td style="padding: 2px;">87,5</td> </tr> <tr> <td style="padding: 2px;">CT (C %) (sec)</td> <td style="padding: 2px;">51,6</td> <td style="padding: 2px;">51,3</td> <td style="padding: 2px;">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
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		2-8°C	RT																		
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Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-12-08 **QC Manager :** S.LECOURT