

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 |

ANALYSIS CERTIFICATE

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 style="text-align: center;">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 style="text-align: center;">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 style="text-align: center;">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 | | | | | | | | | | | | | | | | | |
| aPTT (sec) | 88,5 | 88,6 | 87,5 | | | | | | | | | | | | | | | | | |
| CT (C %) (sec) | 51,6 | 51,3 | 52,1 | | | | | | | | | | | | | | | | | |

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|------------|---|
| Comments : | <input checked="" type="checkbox"/> PASSED IN COMPLIANCE |
|------------|---|

Date : 2017-12-08 **QC Manager :** S.LECOURT