

ANALYSIS CERTIFICATE

FV deficient plasma - # DP020A/DP020K

Lot : F1700454

QC release: 2017-05-11

Expiration date : 2019-10-11

DP020A : 1 mL

DP020K : 6 x 1 mL

Components	Qty	Exp. (months)	LOT	Exp. date
FV deficient plasma	Vial of 1 ml	30	F171100454	2019-10-11



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Lot : F1700454

QC release: 2017-05-11

Expiration date : 2019-10-11

Analytical data	Specifications
1. <u>Within lot reproducibility</u>	
N= 10 PT 57,4 sec CV: 0,4 %	> 35 Sec (CV ≤ 3%)
N= 5 aPTT >250 sec	> 100 Sec

2. <u>Concentration [C]</u>	
FV (ELISA) <1 %	< 1%

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>FV Clotting assay (MC10)</u>											
<table border="1" style="margin: auto;"> <tr> <td style="width: 15%;">V%</td> <td style="width: 15%;">100</td> <td style="width: 15%;">50</td> <td style="width: 15%;">25</td> <td style="width: 15%;">0</td> </tr> <tr> <td>CT (Sec)</td> <td>22,5</td> <td>27,4</td> <td>32,1</td> <td>65,4</td> </tr> </table>	V%	100	50	25	0	CT (Sec)	22,5	27,4	32,1	65,4	CT (0%) > 40 sec CT (100%) < 30sec
V%	100	50	25	0							
CT (Sec)	22,5	27,4	32,1	65,4							

5. <u>Stability of reconstituted reagent</u>													
<table border="1" style="margin: auto;"> <tr> <td></td> <td style="text-align: center;">Fresh</td> <td style="text-align: center;">24h 2-8°C</td> <td style="text-align: center;">8h RT</td> </tr> <tr> <td>PT (sec)</td> <td style="text-align: center;">56,2</td> <td style="text-align: center;">56,1</td> <td style="text-align: center;">55,5</td> </tr> <tr> <td>CT (C%)(sec)</td> <td style="text-align: center;">23,5</td> <td style="text-align: center;">23,4</td> <td style="text-align: center;">23,7</td> </tr> </table>		Fresh	24h 2-8°C	8h RT	PT (sec)	56,2	56,1	55,5	CT (C%)(sec)	23,5	23,4	23,7	Δ ≤ 3 sec Δ ≤ 2 sec
	Fresh	24h 2-8°C	8h RT										
PT (sec)	56,2	56,1	55,5										
CT (C%)(sec)	23,5	23,4	23,7										

Comments :	☑ PASSED IN COMPLIANCE
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Date : 2017-05-11

QC Manager : S.LECOURT

