

ANALYSIS CERTIFICATE

vWFdeficient plasma - # DP150A/DP150K

Lot : F1600298

QC release:

03/05/2016

Expiration date : 2018-10-09

DP150A : 1 mL

DP150K : 6 x 1 mL

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
vWF deficient plasma	Vial of 1 ml	30	F161300298	F161300298	2018-10-09

SAS

ANALYSIS CERTIFICATE

vWFdeficient plasma - # DP150A/DP150K

Lot : F1600298

QC release:

03/05/2016

Expiration date : 2018-10-09

Analytical data	Specifications								
<p>1. <u>Within lot reproducibility</u></p> <p>N= 5 CV 0,6 %</p>	CV ≤ 3%								
<p>2. <u>Concentration [C]</u></p> <p>vWF : (Elisa) < 1 %</p> <p>Factor VIII:C : < 1 %</p> <p>Factor V : 72 %</p>	<p>< 1%</p> <p>< 10%</p> <p>> 50%</p>								
<p>3. <u>Aspect</u></p> <p><input checked="" type="checkbox"/> Slightly opalescent to clear</p> <p><input checked="" type="checkbox"/> No coagulum</p> <p><input checked="" type="checkbox"/> Stable solution</p>	<p>a) Slightly opalescent to clear</p> <p>b) No coagulum</p> <p>c) Stable solution</p>								
<p>4. <u>Stability of reconstituted reagent</u></p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">Fresh</th> <th style="text-align: center;">24h 2-8°C</th> <th style="text-align: center;">8h RT</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">PT (sec)</td> <td style="text-align: center;">15,2</td> <td style="text-align: center;">15,2</td> <td style="text-align: center;">14,8</td> </tr> </tbody> </table>		Fresh	24h 2-8°C	8h RT	PT (sec)	15,2	15,2	14,8	Δ ≤ 1 sec
	Fresh	24h 2-8°C	8h RT						
PT (sec)	15,2	15,2	14,8						

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 03/05/2016 **QC Manager :** S. LECOURT

