

## ANALYSIS CERTIFICATE

**FXII deficient plasma - # DP080A/DP080K**

**Lot : F1600109**

**QC release:**

**07/03/2016**

**Expiration date : 2018-08-11**

**DP080A : 1 mL**

**DP080K : 6 x 1 mL**

<b>Components</b>	<b>Qty</b>	<b>Exp. (months)</b>	<b>Int. Ref.</b>	<b>Lot #</b>	<b>Exp. date</b>
FXII deficient plasma	Vial of 1 ml	30	F161100109	F161100109	2018-08-11

## ANALYSIS CERTIFICATE

**FXII deficient plasma - # DP080A/DP080K**

**Lot : F1600109**

**QC release:**

**07/03/2016**

**Expiration date : 2018-08-11**

Analytical data	Specifications																
<p><b>1. <u>Within lot reproducibility (N ≥ 5)</u></b></p> <p>N= 15                      CV: 0,8 %</p>	CV ≤ 3%																
<p><b>2. <u>Concentration [C]</u></b></p> <p>Factor XII :                      &lt; 1 %</p> <p>Factor V :                              93 %</p>	<p>&lt; 1%</p> <p>&gt; 50%</p>																
<p><b>3. <u>Aspect</u></b></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</p>	<p>a) Slightly opalescent to clear</p> <p>b) No coagulum</p> <p>c) Stable solution</p>																
<p><b>4. <u>FXII Clotting assay</u>                      <u>STAR</u></b></p> <table border="1" style="margin-left: auto; margin-right: auto; border-collapse: collapse;"> <tr> <td style="padding: 2px;">XII%</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;">0</td> </tr> <tr> <td style="padding: 2px;">CT (Sec)</td> <td style="padding: 2px;">56,2</td> <td style="padding: 2px;">69,8</td> <td style="padding: 2px;">87,1</td> <td style="padding: 2px;">111,1</td> <td style="padding: 2px;">&gt; 250</td> </tr> </table>	XII%	100	50	25	12.5	0	CT (Sec)	56,2	69,8	87,1	111,1	> 250	<p>CT (0%) &gt; 180 sec</p> <p>CT (100%) &lt; 65sec</p>				
XII%	100	50	25	12.5	0												
CT (Sec)	56,2	69,8	87,1	111,1	> 250												
<p><b>5. <u>Stability of reconstituted reagent</u></b></p> <table border="1" style="margin-left: auto; margin-right: 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 style="padding: 2px;">PT (sec)</td> <td style="padding: 2px;">14</td> <td style="padding: 2px;">14,4</td> <td style="padding: 2px;">14,2</td> </tr> <tr> <td style="padding: 2px;">CT (C%) (sec)</td> <td style="padding: 2px;">54,7</td> <td style="padding: 2px;">54,8</td> <td style="padding: 2px;">55,5</td> </tr> </table>		Fresh	24h	8h			2-8°C	RT	PT (sec)	14	14,4	14,2	CT (C%) (sec)	54,7	54,8	55,5	<p>Δ ≤ 1 sec</p> <p>Δ ≤ 3 sec</p>
	Fresh	24h	8h														
		2-8°C	RT														
PT (sec)	14	14,4	14,2														
CT (C%) (sec)	54,7	54,8	55,5														

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

**Date :** 07/03/2016                      **QC Manager :** S. LECOURT

