

## ANALYSIS CERTIFICATE

**HEMOCLOT PROTEIN S - # CK041K**

**Lot : 53601**

**QC release: 02/10/2015**

**Expiration date : 2018-03**

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1 : Protein S Deficient Plasma	3 vials	30	150901B	53601-1	2018-03
R2 : Protein S Activator	3 vials	30	150911B	53601-2	2018-03

*SSS*

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Analytical data	Specifications
<b>1. <u>R1 : PS Deficient Plasma</u></b>	
<b>a. <u>PT</u></b>	N ≥ 3 < 15 sec
N = 3 PT = 14,4 sec CV = 1,4 %	
<b>b. <u>APTT</u></b>	N ≥ 3 37 ± 5 sec
N = 3 APTT = 37,8 sec CV = 1,3 %	
<b>c. <u>Fibrinogen content</u></b>	N ≥ 3 ≥ 1.5 g/l
N = 3 Fng = 2,1 g/l	
<b>e. <u>Factor V content</u></b>	N ≥ 3 ≥ 55%
N = 3 FV = 87 %	
<b>f. <u>Factor VIII:C content</u></b>	N ≥ 3 ≥ 45%
N = 3 FVIII:C = 88 %	
<b>g. <u>Aspect</u></b>	Slightly opalescent to clear, No coagulum, Stable solution
<input checked="" type="checkbox"/> Slightly opalescent to clear <input checked="" type="checkbox"/> No coagulum <input checked="" type="checkbox"/> Stable	
<b>2. <u>R2 : Activator</u></b>	
<b>a. <u>Reproducibility (CT)</u></b>	N ≥ 10  CV ≤ 5%
N = 30 CT (0%) = 43,0 sec CV = 1,4 %	
<b>b. <u>Aspect</u></b>	Clear, Transparent
<input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent	

SOS

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<p><b>4. Kit Validation</b></p> <p><b>a. Calibration curve (manual method or KC10)</b></p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th colspan="3">% PS</th> </tr> <tr> <th>Dil</th> <th>%</th> <th>Mean CT</th> </tr> </thead> <tbody> <tr> <td>/</td> <td>0</td> <td>44,6</td> </tr> <tr> <td>1/40</td> <td>25</td> <td>56,9</td> </tr> <tr> <td>1/20</td> <td>50</td> <td>68,3</td> </tr> <tr> <td>1/13,3</td> <td>75</td> <td>81,0</td> </tr> <tr> <td>1/10</td> <td>100</td> <td>95,4</td> </tr> </tbody> </table> <p>Linearity: <math>r^2 =</math> <span style="border: 1px solid black; padding: 2px;">0,9956</span></p> <p>Accuracy:</p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Control</th> <th>TV* (% PS)</th> <th>MV* (% PS)</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td>74</td> <td>72</td> </tr> <tr> <td>Abnormal Control</td> <td>32</td> <td>31</td> </tr> </tbody> </table> <p>* TV= Target Value - MV= Measured Value</p> <p><b>b. Calibration curve (STAR)</b></p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th colspan="3">% PS</th> </tr> <tr> <th>Dil</th> <th>%</th> <th>Mean CT</th> </tr> </thead> <tbody> <tr> <td>/</td> <td>0</td> <td>44,3</td> </tr> <tr> <td>1/40</td> <td>25</td> <td>54,4</td> </tr> <tr> <td>1/20</td> <td>50</td> <td>65,4</td> </tr> <tr> <td>1/15</td> <td>75</td> <td>73,5</td> </tr> <tr> <td>1/10</td> <td>100</td> <td>91,5</td> </tr> </tbody> </table> <p>Linearity: <math>r^2 =</math> 0,9969</p> <p>Accuracy:</p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Control</th> <th>TV* (% PS)</th> <th>MV* (% PS)</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td>74</td> <td>77</td> </tr> <tr> <td>Abnormal Control</td> <td>32</td> <td>31</td> </tr> </tbody> </table> <p>* TV= Target Value - MV= Measured Value</p> <p><b>c. Performances Automate : STAR</b></p> <p>PS deficient plasma) : 0 % PS <span style="float: right;">≤ 10%</span></p> <p>Normal plasmas (N≥ 10): 89 % PS <span style="float: right;">&gt; 60%</span></p> <p style="margin-left: 100px;">Range: 56 - 116</p> <p>Precision Biologic Pool : 111 % PS <span style="float: right;">80-120%</span></p> <p><b>d. Stability of reconstituted reagents</b></p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th rowspan="2">Calibration (%PS)</th> <th rowspan="2">/</th> <th rowspan="2">0%</th> <th>Fresh</th> <th>24h / 2-8°C</th> <th>8h / RT</th> </tr> <tr> <th colspan="3">CT (sec)</th> </tr> </thead> <tbody> <tr> <td>1/40</td> <td>21</td> <td>54,8</td> <td>44,0</td> <td>43,8</td> </tr> <tr> <td>1/20</td> <td>41</td> <td>63,7</td> <td>60,3</td> <td>59,6</td> </tr> <tr> <td>1/15</td> <td>55</td> <td>71,1</td> <td>66,8</td> <td>65,9</td> </tr> <tr> <td>1/8,2</td> <td>100</td> <td>93,8</td> <td>88,7</td> <td>88,5</td> </tr> <tr> <td colspan="2">r2</td> <td></td> <td>0,995</td> <td>0,999</td> <td>0,998</td> </tr> </tbody> </table> <p>Measured values for controls (%PS)</p> <table border="1" style="margin-left: 20px;"> <thead> <tr> <th>Control</th> <th>TV</th> <th>MV</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td>73</td> <td>73</td> </tr> <tr> <td>Abnormal Control</td> <td>30</td> <td>31</td> </tr> </tbody> </table>		% PS			Dil	%	Mean CT	/	0	44,6	1/40	25	56,9	1/20	50	68,3	1/13,3	75	81,0	1/10	100	95,4	Control	TV* (% PS)	MV* (% PS)	Normal Control	74	72	Abnormal Control	32	31	% PS			Dil	%	Mean CT	/	0	44,3	1/40	25	54,4	1/20	50	65,4	1/15	75	73,5	1/10	100	91,5	Control	TV* (% PS)	MV* (% PS)	Normal Control	74	77	Abnormal Control	32	31	Calibration (%PS)	/	0%	Fresh	24h / 2-8°C	8h / RT	CT (sec)			1/40	21	54,8	44,0	43,8	1/20	41	63,7	60,3	59,6	1/15	55	71,1	66,8	65,9	1/8,2	100	93,8	88,7	88,5	r2			0,995	0,999	0,998	Control	TV	MV	Normal Control	73	73	Abnormal Control	30	31	<p>50 ± 10 sec  <math>\Delta</math>CT(100-0%) &gt;40 sec</p> <p>(CT100%) : 90-120sec  (indicative value)  <math>r^2 \geq 0,98</math></p> <p>MV = TV ± 20%  MV = TV ± 20%</p> <p><math>r^2 \geq 0,98</math></p> <p>MV = TV ± 20%  MV = TV ± 20%</p> <p>variations  <math>\Delta</math>CT (0%) ≤ 3 sec  <math>R^2 \geq 0,98</math>  <math>\Delta</math>CT (1:10-0%) ≥ 40 sec</p> <p>[ 63 - 85 ]  [ 26 - 38 ]</p>
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Comments :



**PASSED  
 IN COMPLIANCE**

Date : 02.10.2015

QC Manager :

S.LECOURT

