

ANALYSIS CERTIFICATE

LIAPHEN Fibrinogen (# 120102)

Lot : F1500108

QC Release: 14/01/2016

Expiration date : 2018-05-25

Components	Qty	Exp. (months)	Internal. Ref.	Lot #	Exp. date
R1 : Latex reagent	4 vials	30	F1500038	F1500038	2018-05-25

SAS

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Analytical data	Specifications																																				
<p>3. Calibration curve</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <thead> <tr> <th colspan="2">Manual method</th> <th colspan="2">STA-R method</th> </tr> <tr> <th>Fibrinogen (µg/ml)*</th> <th>A620nm</th> <th>Fibrinogen (µg/ml)*</th> <th>OD/min. 540nm</th> </tr> </thead> <tbody> <tr><td>0</td><td>0,103</td><td>0</td><td>0</td></tr> <tr><td>2,5</td><td>0,151</td><td>5</td><td>0,089</td></tr> <tr><td>5</td><td>0,220</td><td>10</td><td>0,161</td></tr> <tr><td>10</td><td>0,332</td><td>18,75</td><td>0,278</td></tr> <tr><td>15</td><td>0,513</td><td>25</td><td>0,342</td></tr> <tr><td>20</td><td>0,604</td><td>30</td><td>0,379</td></tr> <tr> <td>Linearity (R²):</td> <td>0,996</td> <td>Linearity (R²):</td> <td>0,998</td> </tr> </tbody> </table> <p><small>*concentrations are given in the test dilution</small></p>	Manual method		STA-R method		Fibrinogen (µg/ml)*	A620nm	Fibrinogen (µg/ml)*	OD/min. 540nm	0	0,103	0	0	2,5	0,151	5	0,089	5	0,220	10	0,161	10	0,332	18,75	0,278	15	0,513	25	0,342	20	0,604	30	0,379	Linearity (R ²):	0,996	Linearity (R ²):	0,998	<p>Manuel method:</p> <p>A620 (0µg/ml) < 0.20 ΔA620 (0-20µg/ml) ≥ 0.40</p> <p style="text-align: right;">R² ≥ 0.98</p>
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<p>4. Limit of Quantification</p> <p style="text-align: center;">Method: STA-R</p> <p style="text-align: center;"><0,5 µg/ml, in the test dilution (1:200) i.e : <0,1 g/L in plasma (undiluted)</p>	<p>≤ 1 µg/ml ≤ 0.2 g/L</p>																																				
<p>5. Hook Effect</p> <p style="text-align: center;">Method: STA-R</p> <p style="text-align: center;">110 µg/ml, in the test dilution (1:200) i.e : 22 g/L in plasma (undiluted)</p>	<p>> 90 µg/ml > 18 g/L</p>																																				
<p>6. Accuracy:</p> <p style="text-align: center;">Method: STA-R</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <thead> <tr> <th>Control</th> <th>TV* (Fbg g/L)</th> <th>MV* (Fbg g/L)</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td>2,39</td> <td>2,38</td> </tr> <tr> <td>Abnormal Control</td> <td>1,55</td> <td>1,53</td> </tr> </tbody> </table> <p><small>* TV= Target Value - MV= Measured Value</small></p>	Control	TV* (Fbg g/L)	MV* (Fbg g/L)	Normal Control	2,39	2,38	Abnormal Control	1,55	1,53	<p>[2,15-2,63 g/L] [1,40-1,71 g/L]</p>																											
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<p>7. Performances</p> <p style="text-align: center;">Method: STA-R</p> <p>Normal plasmas: N= 11 Mean= 3,2 g/L Range: 2,6 to 3,5 g/L</p>	<p>N ≥ 10 ~ 1.5 - 5 g/L Fbg Ag</p>																																				
<p>8. Stability of reagents</p> <p style="text-align: center;">Method: STAR</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 5px;"> <thead> <tr> <th>Fibrinogen (µg/ml)</th> <th>Fresh</th> <th>1 week at 30°C</th> </tr> </thead> <tbody> <tr><td>30</td><td>0,389</td><td>0,407</td></tr> <tr><td>25</td><td>0,349</td><td>0,358</td></tr> <tr><td>18,75</td><td>0,294</td><td>0,292</td></tr> <tr><td>10</td><td>0,166</td><td>0,168</td></tr> <tr><td>5</td><td>0,090</td><td>0,087</td></tr> <tr><td>0</td><td>0,001</td><td>0</td></tr> <tr> <td>Linearity (R²):</td> <td>0,998</td> <td>1,00</td> </tr> </tbody> </table> <p>Measured Fbg Ag value for controls :</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td>Normal</td> <td>2,28 g/L</td> <td>2,42 g/L</td> </tr> <tr> <td>Abnormal</td> <td>1,49 g/L</td> <td>1,44 g/L</td> </tr> </tbody> </table>	Fibrinogen (µg/ml)	Fresh	1 week at 30°C	30	0,389	0,407	25	0,349	0,358	18,75	0,294	0,292	10	0,166	0,168	5	0,090	0,087	0	0,001	0	Linearity (R ²):	0,998	1,00	Normal	2,28 g/L	2,42 g/L	Abnormal	1,49 g/L	1,44 g/L	<p>Δ OD or OD/min. ≤ 20% between 5 and 20µg/ml</p> <p style="text-align: right;">r² ≥ 0.98</p> <p style="text-align: center;">[2,15-2,63 g/L] [1,40-1,71 g/L]</p>						
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Comments :



PASSED IN COMPLIANCE

Date : 14/01/2016

QC Manager :

S. LECOURT