

ANALYSIS CERTIFICATE

LIAPHEN Fibrinogen (# 120102)

Lot : F1700178

QC Release: 2017-03-31

Expiration date : 2019-07-28

Components	Qty	Exp. (months)	Lot	Exp. date
R1 : Latex reagent	4 vials	30	F171100178	2019-07-28

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Analytical data	Specifications
1. <u>Latex reagent (R1)</u>	
Volume: N= 5 Mean: >5 ml	≥ 5.0 ml
Reproducibility (20 µg/ml Fibrinogen): Method: W.Bath	
N = 15 Mean : 0,603 CV: 1,2 %	≤ 3 %

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<p>3. Calibration curve</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <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>0,102</td><td>0</td><td>0,002</td></tr> <tr><td>2,5</td><td>0,153</td><td>5</td><td>0,082</td></tr> <tr><td>5</td><td>0,221</td><td>10</td><td>0,159</td></tr> <tr><td>10</td><td>0,382</td><td>18,75</td><td>0,266</td></tr> <tr><td>15</td><td>0,528</td><td>25</td><td>0,317</td></tr> <tr><td>20</td><td>0,643</td><td>30</td><td>0,355</td></tr> <tr><td>Linearity (R²):</td><td>0,999</td><td>Linearity (R²):</td><td>0,999</td></tr> </tbody> </table> <p>*concentrations are given in the test dilution</p>	Manual method		STA-R method		Fibrinogen (µg/ml)*	A620nm	Fibrinogen (µg/ml)*	OD/min. 540nm	0	0,102	0	0,002	2,5	0,153	5	0,082	5	0,221	10	0,159	10	0,382	18,75	0,266	15	0,528	25	0,317	20	0,643	30	0,355	Linearity (R²):	0,999	Linearity (R²):	0,999	<p style="text-align: center;">Manuel method:</p> <p style="text-align: center;">A620 (0µg/ml) < 0.20 ΔA620 (0-20µg/ml) ≥ 0.40</p> <p style="text-align: center;">R² ≥ 0.98</p>
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<p>4. Limit of Quantification</p> <p style="text-align: center;">Method: STA-R 0,25 µg/ml, in the test dilution (1:200) i.e : 0,05 g/L in plasma (undiluted)</p>	<p style="text-align: center;">≤ 1 µg/ml ≤ 0.2 g/L</p>																																				
<p>5. Hook Effect</p> <p style="text-align: center;">Method: STA-R 110 µg/ml, in the test dilution (1:200) i.e : 22 g/L in plasma (undiluted)</p>	<p style="text-align: center;">> 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; text-align: center;"> <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>2,72</td><td>2,73</td></tr> <tr><td>Abnormal Control</td><td>1,55</td><td>1,53</td></tr> </tbody> </table> <p>* TV= Target Value - MV= Measured Value</p>	Control	TV* (Fbg g/L)	MV* (Fbg g/L)	Normal Control	2,72	2,73	Abnormal Control	1,55	1,53	<p style="text-align: center;">[2,45 - 2,99 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= 10 Mean= 3,7 g/L Range: 2,3 to 4,5 g/L</p>	<p style="text-align: center;">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; text-align: center;"> <thead> <tr> <th>Fibrinogen (µg/ml)</th> <th>Fresh</th> <th>1 week at 30°C</th> </tr> </thead> <tbody> <tr><td>0</td><td>0,005</td><td>0,002</td></tr> <tr><td>5</td><td>0,077</td><td>0,076</td></tr> <tr><td>10</td><td>0,159</td><td>0,149</td></tr> <tr><td>18,75</td><td>0,252</td><td>0,263</td></tr> <tr><td>25</td><td>0,303</td><td>0,319</td></tr> <tr><td>30</td><td>0,347</td><td>0,342</td></tr> <tr><td>Linearity (R²):</td><td>0,998</td><td>0,996</td></tr> </tbody> </table> <p>Measured Fbg Ag value for controls :</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <tbody> <tr><td>Normal</td><td>2,72 g/L</td><td>2,61 g/L</td></tr> <tr><td>Abnormal</td><td>1,54 g/L</td><td>1,58 g/L</td></tr> </tbody> </table>	Fibrinogen (µg/ml)	Fresh	1 week at 30°C	0	0,005	0,002	5	0,077	0,076	10	0,159	0,149	18,75	0,252	0,263	25	0,303	0,319	30	0,347	0,342	Linearity (R²):	0,998	0,996	Normal	2,72 g/L	2,61 g/L	Abnormal	1,54 g/L	1,58 g/L	<p style="text-align: center;">Δ OD or OD/min. ≤ 20% between 5 and 20µg/ml</p> <p style="text-align: center;">R² ≥ 0.98</p> <p style="text-align: center;">[2,45 - 2,99 g/L] [1,40 - 1,71 g/L]</p>						
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Comments :



PASSED IN COMPLIANCE

Date : 2017-03-31

QC Manager :

S.LECOURT