

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 |

923

ANALYSIS CERTIFICATE

LIAPHEN Fibrinogen (# 120102)

Lot : F1700178

QC Release: 2017-03-31

Expiration date : 2019-07-28

| 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 % |

903

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| Analytical data | Specifications | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|--|------------------------------|----------------|----------------|---------------------|--------|---------------------|---------------|-------|-------|-------|-------|-------|-------|-------|-------|-------|-------|----|-------|-------|------------------------------|-------|-------|--------|----------|----------|----------|----------|----------|---|-------|------------------------------|-------|------------------------------|-------|--|
| 3. Calibration curve | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"><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 (R ²): | 0,999 | Linearity (R ²): | 0,999 | <p>Manuel method:</p> <p>A620 (0µg/ml) < 0.20 ΔA620 (0-20µg/ml) ≥ 0.40</p> <p>R² ≥ 0.98</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 (R ²): | 0,999 | Linearity (R ²): | 0,999 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 4. Limit of Quantification | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Method: STA-R 0,25 µg/ml, in the test dilution (1:200) i.e : 0,05 g/L in plasma (undiluted) | ≤ 1 µg/ml ≤ 0.2 g/L | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 5. Hook Effect | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Method: STA-R 110 µg/ml, in the test dilution (1:200) i.e : 22 g/L in plasma (undiluted) | > 90 µg/ml > 18 g/L | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 6. Accuracy: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Method: STA-R | [2,45 - 2,99 g/L] [1,40 - 1,71 g/L] | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"><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 | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Control | TV* (Fbg g/L) | MV* (Fbg g/L) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Normal Control | 2,72 | 2,73 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Abnormal Control | 1,55 | 1,53 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 7. Performances | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Method: STA-R Normal plasmas: N= 10 Mean= 3,7 g/L Range: 2,3 to 4,5 g/L | N ≥ 10 ~ 1.5 - 5 g/L Fbg Ag | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 8. Stability of reagents | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Method: STAR | Δ OD or OD/min. ≤ 20% between 5 and 20µg/ml | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"><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;"><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 (R ²): | 0,998 | 0,996 | Normal | 2,72 g/L | 2,61 g/L | Abnormal | 1,54 g/L | 1,58 g/L | R² ≥ 0.98 [2,45 - 2,99 g/L] [1,40 - 1,71 g/L] | | | | | | |
| 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 (R ²): | 0,998 | 0,996 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Normal | 2,72 g/L | 2,61 g/L | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Abnormal | 1,54 g/L | 1,58 g/L | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Comments :



PASSED IN COMPLIANCE

Date : 2017-03-31

QC Manager :

S.LECOURT

