

ANALYSIS CERTIFICATE

LIAPHEN AT (# 120002)

Lot : F1600321

QC Release: 11/03/2016

Expiration date : 2018-08-03

Components	Qty	Exp. (months)	Internal. Ref.	Lot #	Exp. date
R1 : Latex reagent	2 vials	30	F161100202	F161100202	2018-08-03
R2 : Reaction Buffer	2 vials	30	F161100201	F161100201	2018-08-10

S 03

ANALYSIS CERTIFICATE

LIAPHEN AT (# 120002)

Lot : F1600321

QC Release: 11/03/2016

Expiration date : 2018-08-03

Analytical data	Specifications
<p>1. <u>Latex reagent (R1)</u> Method : Water bath</p> <p>Reproducibility (100 % AT): N = 15 Mean : 0,517 CV: 1,4 %</p>	<p>N ≥ 10 ≤ 3 %</p>
<p>2. <u>Reaction Buffer (R2)</u></p> <p style="text-align: right;">Volume: > 10 ml</p> <p style="text-align: right;">pH 8,00</p> <p>Aspect: <input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent</p>	<p>≥ 10 ml [7.80 - 8.20] Clear - Transparent</p>

SJS

ANALYSIS CERTIFICATE

LIAPHEN AT (# 120002)

Lot : F1600321

QC Release: 11/03/2016

Expiration date : 2018-08-03

Analytical data	Specifications																																								
<p>3. Calibration curve</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-bottom: 10px;"> <thead> <tr> <th colspan="2" style="text-align: center;">AT (%)</th> <th style="text-align: center;">A620nm</th> <th style="text-align: center;">DOD540nm</th> </tr> <tr> <th colspan="2"></th> <th style="text-align: center;">Manual</th> <th style="text-align: center;">STAR</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>0</td> <td style="text-align: center;">0,079</td> <td style="text-align: center;">-0,004</td> </tr> <tr> <td>C:4</td> <td>25</td> <td style="text-align: center;">0,147</td> <td style="text-align: center;">0,025</td> </tr> <tr> <td>C:2</td> <td>50</td> <td style="text-align: center;">0,252</td> <td style="text-align: center;">0,071</td> </tr> <tr> <td>0.75°C</td> <td>75</td> <td style="text-align: center;">0,372</td> <td style="text-align: center;">0,117</td> </tr> <tr> <td>C</td> <td>100</td> <td style="text-align: center;">0,509</td> <td style="text-align: center;">0,164</td> </tr> <tr> <td>1.5°C</td> <td>150</td> <td style="text-align: center;">0,749</td> <td style="text-align: center;">0,249</td> </tr> <tr> <td colspan="2">Linearity: R² =</td> <td style="text-align: center;">0,9980</td> <td style="text-align: center;">0,9990</td> </tr> <tr> <td colspan="2">Interpolation:</td> <td style="text-align: center;">polynomial degree 3</td> <td style="text-align: center;">polynomial degree 3</td> </tr> </tbody> </table>	AT (%)		A620nm	DOD540nm			Manual	STAR	0	0	0,079	-0,004	C:4	25	0,147	0,025	C:2	50	0,252	0,071	0.75°C	75	0,372	0,117	C	100	0,509	0,164	1.5°C	150	0,749	0,249	Linearity: R ² =		0,9980	0,9990	Interpolation:		polynomial degree 3	polynomial degree 3	<p style="text-align: center;">Manual:</p> <p style="text-align: center;">A620 (0%) ≤ 0.15 ΔA620 (0-150%) ≥ 0.40</p> <p style="text-align: center; margin-top: 20px;">R² ≥ 0.98</p>
AT (%)		A620nm	DOD540nm																																						
		Manual	STAR																																						
0	0	0,079	-0,004																																						
C:4	25	0,147	0,025																																						
C:2	50	0,252	0,071																																						
0.75°C	75	0,372	0,117																																						
C	100	0,509	0,164																																						
1.5°C	150	0,749	0,249																																						
Linearity: R ² =		0,9980	0,9990																																						
Interpolation:		polynomial degree 3	polynomial degree 3																																						
<p>4. Detection threshold</p> <p style="text-align: right;">Method: STAR 7 %</p>	<p>≤ 10 %</p>																																								
<p>5. Hook Effect</p> <p style="text-align: right;">Method: STAR > 200 %</p>	<p>> 200%</p>																																								
<p>6. Accuracy:</p> <p style="text-align: right;">Method: STAR</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th style="text-align: left;">Control</th> <th style="text-align: center;">TV* (% AT)</th> <th style="text-align: center;">MV* (% AT)</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td style="text-align: center;">86</td> <td style="text-align: center;">87</td> </tr> <tr> <td>Abnormal Control</td> <td style="text-align: center;">34</td> <td style="text-align: center;">35</td> </tr> </tbody> </table> <p><small>* TV= Target Value - MV= Measured Value</small></p>	Control	TV* (% AT)	MV* (% AT)	Normal Control	86	87	Abnormal Control	34	35	<p>[76 - 96] [29 - 39]</p>																															
Control	TV* (% AT)	MV* (% AT)																																							
Normal Control	86	87																																							
Abnormal Control	34	35																																							
<p>7. Performances</p> <p style="text-align: right;">Method: STAR</p> <p>Normal plasmas: N= 10 Mean= 101 % Range: 91 to 110 %</p>	<p>N ≥ 10 Indicative : ~ 80% - 130% AT</p>																																								
<p>8. Stability of reagents</p> <p>Method: ...</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th></th> <th style="text-align: center;">Fresh</th> <th style="text-align: center;">1 week at RT</th> </tr> </thead> <tbody> <tr> <td>0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> <tr> <td>C:4</td> <td style="text-align: center;">0,024</td> <td style="text-align: center;">0,023</td> </tr> <tr> <td>C:2</td> <td style="text-align: center;">0,067</td> <td style="text-align: center;">0,065</td> </tr> <tr> <td>0.75°C</td> <td style="text-align: center;">0,111</td> <td style="text-align: center;">0,109</td> </tr> <tr> <td>C</td> <td style="text-align: center;">0,159</td> <td style="text-align: center;">0,156</td> </tr> <tr> <td>1.5°C</td> <td style="text-align: center;">0,232</td> <td style="text-align: center;">0,229</td> </tr> <tr> <td>R²</td> <td style="text-align: center;">1,000</td> <td style="text-align: center;">1,000</td> </tr> <tr> <td colspan="3">Measured AT value for controls :</td> </tr> <tr> <td>Normal</td> <td style="text-align: center;">85%</td> <td style="text-align: center;">89%</td> </tr> <tr> <td>Abnormal</td> <td style="text-align: center;">36%</td> <td style="text-align: center;">36%</td> </tr> </tbody> </table>		Fresh	1 week at RT	0	0	0	C:4	0,024	0,023	C:2	0,067	0,065	0.75°C	0,111	0,109	C	0,159	0,156	1.5°C	0,232	0,229	R ²	1,000	1,000	Measured AT value for controls :			Normal	85%	89%	Abnormal	36%	36%	<p>Δ OD or DOD ≤ 10% for 1.5C, C and 0.75°C</p> <p>R² ≥ 0.98</p> <p>[76 - 96] [29 - 39]</p>							
	Fresh	1 week at RT																																							
0	0	0																																							
C:4	0,024	0,023																																							
C:2	0,067	0,065																																							
0.75°C	0,111	0,109																																							
C	0,159	0,156																																							
1.5°C	0,232	0,229																																							
R ²	1,000	1,000																																							
Measured AT value for controls :																																									
Normal	85%	89%																																							
Abnormal	36%	36%																																							

Comments :



PASSED IN COMPLIANCE

Date : 11/03/2016

QC Manager :

S. LECOURT