

## ANALYSIS CERTIFICATE

**LIAPHEN AT (# 120002)**

**Lot : F1700800  
F1700801**

**QC Release: 2017-11-06**

**Expiration date : 2020-01-04**

<b>Components</b>	<b>Qty</b>	<b>Exp. (months)</b>	<b>Lot</b>	<b>Exp. date</b>
R1 : Latex reagent	2 vials	30	F171300800 F171100801	2020-03-28
R2 : Reaction Buffer	2 vials	30	F171300800 F171100801	2020-01-04



## ANALYSIS CERTIFICATE

LIAPHEN AT (# 120002)

F1700800  
 Lot : F1700801

QC Release: 2017-11-06

Expiration date : 2020-01-04

Analytical data	Specifications																																								
<b>3. Calibration curve</b>																																									
<table border="1" style="margin: auto; border-collapse: collapse;"> <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 style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0,076</td> <td style="text-align: center;">- 0,004</td> </tr> <tr> <td style="text-align: center;">C:4</td> <td style="text-align: center;">25</td> <td style="text-align: center;">0,134</td> <td style="text-align: center;">0,017</td> </tr> <tr> <td style="text-align: center;">C:2</td> <td style="text-align: center;">50</td> <td style="text-align: center;">0,212</td> <td style="text-align: center;">0,050</td> </tr> <tr> <td style="text-align: center;">0,75°C</td> <td style="text-align: center;">75</td> <td style="text-align: center;">0,298</td> <td style="text-align: center;">0,088</td> </tr> <tr> <td style="text-align: center;">C</td> <td style="text-align: center;">100</td> <td style="text-align: center;">0,421</td> <td style="text-align: center;">0,130</td> </tr> <tr> <td style="text-align: center;">1,5°C</td> <td style="text-align: center;">150</td> <td style="text-align: center;">0,615</td> <td style="text-align: center;">0,189</td> </tr> <tr> <td colspan="2">Linearity: R<sup>2</sup> =</td> <td style="text-align: center;">0,999</td> <td style="text-align: center;">1,00</td> </tr> <tr> <td colspan="2">Interpolation:</td> <td style="text-align: center;">poly 3</td> <td style="text-align: center;">poly 3</td> </tr> </tbody> </table>	AT (%)		A620nm	DOD540nm			Manual	STAR	0	0	0,076	- 0,004	C:4	25	0,134	0,017	C:2	50	0,212	0,050	0,75°C	75	0,298	0,088	C	100	0,421	0,130	1,5°C	150	0,615	0,189	Linearity: R <sup>2</sup> =		0,999	1,00	Interpolation:		poly 3	poly 3	<p>Manual:</p> <p>A620 (0%) ≤ 0.15  <math>\Delta A620 (0-150\%) \geq 0.40</math></p> <p>R<sup>2</sup> ≥ 0.98</p>
AT (%)		A620nm	DOD540nm																																						
		Manual	STAR																																						
0	0	0,076	- 0,004																																						
C:4	25	0,134	0,017																																						
C:2	50	0,212	0,050																																						
0,75°C	75	0,298	0,088																																						
C	100	0,421	0,130																																						
1,5°C	150	0,615	0,189																																						
Linearity: R <sup>2</sup> =		0,999	1,00																																						
Interpolation:		poly 3	poly 3																																						
<b>4. Detection threshold</b>																																									
Method: STAR	6 %																																								
<b>5. Hook Effect</b>																																									
Method: STAR	> 250 %																																								
<b>6. Accuracy:</b>																																									
Method: STAR	STAR																																								
<table border="1" style="margin: auto; border-collapse: collapse;"> <thead> <tr> <th>Control</th> <th>TV* (% AT)</th> <th>MV* (% AT)</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td style="text-align: center;">90</td> <td style="text-align: center;">93</td> </tr> <tr> <td>Abnormal Control</td> <td style="text-align: center;">34</td> <td style="text-align: center;">35</td> </tr> </tbody> </table>	Control	TV* (% AT)	MV* (% AT)	Normal Control	90	93	Abnormal Control	34	35	<p>[80 - 100]            [29 - 39]</p>																															
Control	TV* (% AT)	MV* (% AT)																																							
Normal Control	90	93																																							
Abnormal Control	34	35																																							
* TV= Target Value - MV= Measured Value																																									
<b>7. Performances</b>																																									
Method: STAR	STAR																																								
Normal plasmas: N=	11																																								
Mean=	111 %																																								
Range:	100 to 128 %																																								
<b>8. Stability of reagents</b>																																									
Method: STAR	STAR																																								
<table border="1" style="margin: auto; border-collapse: collapse;"> <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 style="text-align: center;">0</td> <td style="text-align: center;">0</td> <td style="text-align: center;">0</td> </tr> <tr> <td style="text-align: center;">C:4</td> <td style="text-align: center;">0,014</td> <td style="text-align: center;">0,014</td> </tr> <tr> <td style="text-align: center;">C:2</td> <td style="text-align: center;">0,045</td> <td style="text-align: center;">0,043</td> </tr> <tr> <td style="text-align: center;">0,75°C</td> <td style="text-align: center;">0,077</td> <td style="text-align: center;">0,077</td> </tr> <tr> <td style="text-align: center;">C</td> <td style="text-align: center;">0,117</td> <td style="text-align: center;">0,113</td> </tr> <tr> <td style="text-align: center;">1,5°C</td> <td style="text-align: center;">0,179</td> <td style="text-align: center;">0,171</td> </tr> <tr> <td style="text-align: center;">R<sup>2</sup></td> <td style="text-align: center;">0,998</td> <td style="text-align: center;">1,00</td> </tr> <tr> <td colspan="3">Measured AT value for controls :</td> </tr> <tr> <td style="text-align: center;">Normal</td> <td style="text-align: center;">93 %</td> <td style="text-align: center;">93 %</td> </tr> <tr> <td style="text-align: center;">Abnormal</td> <td style="text-align: center;">35 %</td> <td style="text-align: center;">35 %</td> </tr> </tbody> </table>		Fresh	1 week at RT	0	0	0	C:4	0,014	0,014	C:2	0,045	0,043	0,75°C	0,077	0,077	C	0,117	0,113	1,5°C	0,179	0,171	R <sup>2</sup>	0,998	1,00	Measured AT value for controls :			Normal	93 %	93 %	Abnormal	35 %	35 %	<p><math>\Delta OD</math> or DOD ≤ 10%            for 1.5C, C and 0.75°C</p> <p>R<sup>2</sup> ≥ 0.98</p> <p>[80 - 100]            [29 - 39]</p>							
	Fresh	1 week at RT																																							
0	0	0																																							
C:4	0,014	0,014																																							
C:2	0,045	0,043																																							
0,75°C	0,077	0,077																																							
C	0,117	0,113																																							
1,5°C	0,179	0,171																																							
R <sup>2</sup>	0,998	1,00																																							
Measured AT value for controls :																																									
Normal	93 %	93 %																																							
Abnormal	35 %	35 %																																							

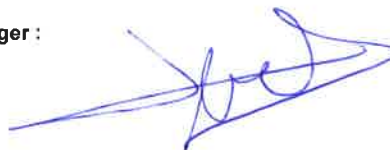
Comments :



PASSED IN  
COMPLIANCE

Date : 2017-11-06

QC Manager :



S. LECOURT