

CERTIFICATE
of ANALYSIS

BIOPHEN® AT anti-(h)-Xa LRT (#221123)

Lot : F1700969

QC Release: 2017-09-18

Expiration date : 2019-08-18

Reagents	Volume	Exp. (months)	Lot #	Exp. date
R1 : Human FXa	3mL	24	F171400969	2019-08-18
R2 : FXa Substrate	3mL	24	F171400969	2019-08-18

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Analytical data	Specifications
<p>1. Human Factor Xa</p> <p>a. Reproducibility (0% AT)</p> <p>Method: WB N : 5 Mean (A405): 1,780 CV: 0,7 %</p> <p>b. Factor Xa aspect</p> <p><input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent</p> <p>c. FXa volume:</p> <p>N : 3 Volume: >3</p>	<p>≤ 2 %</p> <p>Clear, Transparent</p> <p>N ≥ 3 V ≥ 3mL</p>

<p>2. SXa-11 substrate</p> <p>a. Blank value (N=10) Mean (A405): 0,145</p> <p>b. Stability of substrate blank (A405)</p> <table border="1"> <thead> <tr> <th>Time</th> <th>Fresh</th> <th>7 days</th> </tr> </thead> <tbody> <tr> <td>2-8°C</td> <td>0,145</td> <td>0,143</td> </tr> <tr> <td>R.T.</td> <td>0,145</td> <td>0,144</td> </tr> </tbody> </table> <p>c. Reproducibility (0% AT)</p> <p>Method: WB N : 5 Mean (A405): 1,772 CV: 0,8 %</p> <p>d. Substrate aspect</p> <p><input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent <input checked="" type="checkbox"/> Slightly yellow</p> <p>e. Substrate volume:</p> <p>N : 3 Volume: >3</p>	Time	Fresh	7 days	2-8°C	0,145	0,143	R.T.	0,145	0,144	<p>A405 ≤ 0.300</p> <p>A405: 7 days ≤ 0.300 7 days ≤ 0.300</p> <p>≤ 2 %</p> <p>Clear, Transparent Slightly yellow</p> <p>N ≥ 3 V ≥ 3mL</p>
Time	Fresh	7 days								
2-8°C	0,145	0,143								
R.T.	0,145	0,144								

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Analytical data		Specifications														
1. Calibration curve (CS) Instrument: CS <table border="1"> <thead> <tr> <th>%AT</th> <th>ΔA405/min</th> </tr> </thead> <tbody> <tr><td>150</td><td>0,644</td></tr> <tr><td>100</td><td>1,084</td></tr> <tr><td>50</td><td>1,512</td></tr> <tr><td>25</td><td>1,715</td></tr> <tr><td>12.5</td><td>1,828</td></tr> <tr><td>0</td><td>1,920</td></tr> </tbody> </table> Linearity: R ² = 1,00		%AT	ΔA405/min	150	0,644	100	1,084	50	1,512	25	1,715	12.5	1,828	0	1,920	CS ΔA405(100-50%) ≥ 0.25 ΔA405(100%) = 1.00 ± 0.25 R ² ≥ 0.98
%AT	ΔA405/min															
150	0,644															
100	1,084															
50	1,512															
25	1,715															
12.5	1,828															
0	1,920															
2. Detection threshold (LOQ) Instrument: CS 3 %		≤ 10 %														
3. Accuracy: Instrument: CS <table border="1"> <thead> <tr> <th>Control</th> <th>TV* (% AT)</th> <th>MV* (%AT)</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td align="center">88</td> <td align="center">87</td> </tr> <tr> <td>Abnormal Control</td> <td align="center">34</td> <td align="center">34</td> </tr> </tbody> </table> * TV= Target Value - MV= Measured Value		Control	TV* (% AT)	MV* (%AT)	Normal Control	88	87	Abnormal Control	34	34	Measured value in compliance [78 - 98] [29 - 39]					
Control	TV* (% AT)	MV* (%AT)														
Normal Control	88	87														
Abnormal Control	34	34														
4. Performances Instrument: CS Normal plasmas: N= 11 Mean= 105 % Range: 89 to 124 % Specificity: AT poor plasma: 3 %		N ≥ 10 > 80 to about 130% AT ≤ 10%														

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Analytical data			Specifications
5. Stability of reagents (A405) Instrument: CS			
%AT	Fresh	1 week at 18-25°C	
150	0,599	0,633	
100	1,063	1,052	
50	1,487	1,494	
25	1,715	1,714	
12.5	1,830	1,827	
0	1,931	1,927	
R ²	1,00	1,00	
Normal Control	87 %	87 %	
Abnormal Control	35 %	35 %	
			CS: $\Delta A_{405}(100-50\%) \geq 0.25$ $\Delta A_{405}(100\%) = 1.00 \pm 0.25$ $R^2 \geq 0.98$ [78 - 98] [29 - 39]

Comments :



**PASSED IN
COMPLIANCE**

Date : 2017-10-06

QC Manager :

S. LECOURT

