

ANALYSIS CERTIFICATE

BIOPHEN AT (anti-IIa) - # 221122

Lot : F1601207

QC Release : 2017-01-18

Expiration date : 2019-05-11

Components	Qty	Exp. (months)	Lot #	Exp. date
R1 : Bovine Thrombin	2 vials	30	F161201207	2019-05-21
R2 : Thrombin Substrate	2 vials	30	F161201207	2019-05-11
R3 : Tris-Heparin Buffer	2 vials	30	F161201207	2019-05-12

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Analytical data	Specifications									
<p>1. <u>Bovine Thrombin (R1)</u></p> <p>a. Reproducibility (0% AT):</p> <p style="margin-left: 40px;">N = 5 Mean (A405): 1,855</p> <p style="margin-left: 80px;">CV(OD) : 1,1 %</p>	<p>≤ 2 %</p>									
<p>2. <u>Thrombin substrate (R2)</u> (tested at 1 mg/ml for a,b)</p> <p>a. Blank value (N=10) Mean (A405): 0,100</p> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="margin-left: 40px; border-collapse: collapse; text-align: center;"> <thead> <tr> <th style="width: 20%;">Time</th> <th style="width: 20%;">Fresh</th> <th style="width: 20%;">7 days</th> </tr> </thead> <tbody> <tr> <td>2-8°C</td> <td>0,094</td> <td>0,097</td> </tr> <tr> <td>R.T. (18-25°C)</td> <td style="background-color: #cccccc;"></td> <td>0,095</td> </tr> </tbody> </table> <p>c. Reproducibility (0% AT):</p> <p style="margin-left: 40px;">N = 5 Mean (A405): 1,866</p> <p style="margin-left: 80px;">CV(OD) : 1,3 %</p>	Time	Fresh	7 days	2-8°C	0,094	0,097	R.T. (18-25°C)		0,095	<p>A405 ≤ 0.30</p> <p>A405</p> <p>7 days ≤ 0.30</p> <p>≤ 2 %</p>
Time	Fresh	7 days								
2-8°C	0,094	0,097								
R.T. (18-25°C)		0,095								
<p>3. <u>Tris Heparin buffer (R3)</u></p> <p style="margin-left: 40px;">N = 5</p> <p style="margin-left: 40px;">Aspect: Clear , transparent</p> <p style="margin-left: 40px;">Volume: >25 ml</p> <p style="margin-left: 40px;">pH: 8,41</p>	<p>N ≥ 3</p> <p>Clear, transparent</p> <p>≥ 25ml</p> <p>8.40 ± 0.20</p>									

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Analytical data				Specifications
1. Calibration curve				$\Delta A405(0-100\%) \geq 0.80$ $R^2 \geq 0.98$
%AT		A405 W. Bath	Δ A405 STAR	
0 %	0	1,888	2,217	
C:8 or C:10	12,5	1,719	2,034	
C:4	25	1,529	1,852	
C:2	50	1,195	1,454	
C =	100%	0,600	0,757	
Linearity: $R^2 =$		0,998	0,9980	

2. Detection threshold		Method: STAR	<1 %	≤ 10 %
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3. Accuracy: STAR			[76 - 96]
Control	TV* (% AT)	MV* (%AT)	[29 - 39]
Normal Control	86	88	
Abnormal Control	34	35	
* TV= Target Value - MV= Measured Value			

4. Performances STAR		N = 13	N ≥ 10
Normal plasmas:	Mean=	122 %	>70% to about 120%
Range: 94 to 138 %			
AT Depleted Plasma:	10	%AT	≤ 15 %

5. Stability of restored reagents					$\Delta A405$ (Fresh/Stored reagent) $\leq 10\%$ $R^2 \geq 0.98$ [76 - 96] [29 - 39]
Method: Automated (STAR)					
	Fresh	7 days RT	15 days 2-8°C	Frozen	
0	2,199	2,253	2,242	2,253	
C:8 or C:10	2,050	2,072	2,066	2,065	
C:4	1,841	1,884	1,852	1,855	
C:2	1,480	1,477	1,483	1,475	
C	0,816	0,781	0,794	0,795	
R^2	0,998	0,998	0,998	0,996	
Normal Control	91 %	89 %	92 %	89 %	
Abnormal Control	35 %	38 %	35 %	36%	

Comments : 	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-01-18

QC Manager : S.LECOURT

