

ANALYSIS CERTIFICATE

BIOPHEN PROTEIN C 5 - #221205

Lot : F1700804

QC release: 2017-08-30

Expiration date : 2020-01-13

Components	Volume	Exp. (months)	Lot #	Exp. date
R1 : PROTAC® 0.80 IU	4 vials	30	F171200804	2020-01-19
R2 : SaPC-21 - 4 mg	4 vials	30	F171200804	2020-01-13

gfb

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Analytical data	Specifications									
<p>1. <u>SaPC-21 substrate</u></p> <p>a. Blank value (N=10) Mean (A405): 0,167</p> <p>b. Stability of substrate blank (A405)</p> <table border="1" style="margin-left: 20px; border-collapse: collapse;"> <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 style="text-align: center;">2-8°C</td> <td style="text-align: center;">0,149</td> <td style="text-align: center;">0,151</td> </tr> <tr> <td style="text-align: center;">R.T.</td> <td style="text-align: center;">0,150</td> <td style="text-align: center;">0,150</td> </tr> </tbody> </table> <p>c. Reproducibility (100% APC) (manual method)</p> <p style="margin-left: 40px;">N= 15 Mean (A405): 1,203</p> <p style="margin-left: 100px;">CV(DO): 1,15 %</p> <p>d. Substrate aspect</p> <p><input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent <input checked="" type="checkbox"/> Slightly yellow</p>	Time	Fresh	7 days	2-8°C	0,149	0,151	R.T.	0,150	0,150	<p style="text-align: center;">A405 ≤ 0.30</p> <p style="text-align: center;">A405: 7 days 2-8° C ≤ 0.30 7 days R.T. ≤ 0.30</p> <p style="text-align: center;">A405 ≥ 0,80 ≤ 2 %</p> <p style="text-align: center;">Clear, Transparent Slightly yellow</p>
Time	Fresh	7 days								
2-8°C	0,149	0,151								
R.T.	0,150	0,150								

<p>2. <u>Protac® : Activated Protein C Activator</u></p> <p>a. Reproducibility (100% PC) (manual method)</p> <p style="margin-left: 40px;">N= 15 Mean (A405): 1,175</p> <p style="margin-left: 100px;">CV(DO): 1,39 %</p> <p>b. Protac® aspect</p> <p><input checked="" type="checkbox"/> Clear <input checked="" type="checkbox"/> Transparent</p>	<p style="text-align: center;">A405 ≥ 0,80 ≤ 2 %</p> <p style="text-align: center;">Clear, Transparent</p>
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Analytical data	Specifications																				
3. Validation of PC method																					
a. Calibration curve (manual)																					
<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="2">%PC</th> <th>A405</th> </tr> </thead> <tbody> <tr> <td colspan="2" style="text-align: center;">0</td> <td style="text-align: center;">0,005</td> </tr> <tr> <td style="text-align: center;">C/4</td> <td style="text-align: center;">25</td> <td style="text-align: center;">0,315</td> </tr> <tr> <td style="text-align: center;">C/2</td> <td style="text-align: center;">50</td> <td style="text-align: center;">0,599</td> </tr> <tr> <td style="text-align: center;">C</td> <td style="text-align: center;">100</td> <td style="text-align: center;">1,202</td> </tr> </tbody> </table>	%PC		A405	0		0,005	C/4	25	0,315	C/2	50	0,599	C	100	1,202	<p>100% PC: A405 ≥ 0,80</p> <p>0% PC: A405 ≤ 0.10</p>					
%PC		A405																			
0		0,005																			
C/4	25	0,315																			
C/2	50	0,599																			
C	100	1,202																			
b. Linearity Method : Water bath (manual)																					
$R^2 = 0,9997$	$R^2 \geq 0.98$																				
c. Detection threshold Method : STAR																					
<p>(0%PC) Mean (A405): 0,001</p> <p>SD: 0,001</p> <p>Mean (A405) + 3 SD: 0,004</p> <p>% PC: <5</p>	<p>≤ 0.10</p> <p>≤ 5%</p>																				
d. Accuracy																					
<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Control</th> <th>TV* % PC</th> <th>MV* % PC</th> </tr> </thead> <tbody> <tr> <td>Normal Control</td> <td style="text-align: center;">89</td> <td style="text-align: center;">92</td> </tr> <tr> <td>Abnormal Control</td> <td style="text-align: center;">38</td> <td style="text-align: center;">36</td> </tr> </tbody> </table> <p>* TV= Target Value - MV= Measured Value</p>	Control	TV* % PC	MV* % PC	Normal Control	89	92	Abnormal Control	38	36	<p>MV = TV ± 5%</p> <p>MV = TV ± 8%</p>											
Control	TV* % PC	MV* % PC																			
Normal Control	89	92																			
Abnormal Control	38	36																			
e. Stability of calibration curve																					
<table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>% PC</th> <th>0</th> <th>26</th> <th>52</th> <th>104</th> </tr> </thead> <tbody> <tr> <td>Fresh</td> <td style="text-align: center;">0,001</td> <td style="text-align: center;">0,126</td> <td style="text-align: center;">0,251</td> <td style="text-align: center;">0,509</td> </tr> <tr> <td>7 days at 2-8°C</td> <td style="text-align: center;">0,002</td> <td style="text-align: center;">0,127</td> <td style="text-align: center;">0,249</td> <td style="text-align: center;">0,507</td> </tr> <tr> <td>7 days at RT (18-25°C)</td> <td style="text-align: center;">0,002</td> <td style="text-align: center;">0,122</td> <td style="text-align: center;">0,249</td> <td style="text-align: center;">0,505</td> </tr> </tbody> </table>	% PC	0	26	52	104	Fresh	0,001	0,126	0,251	0,509	7 days at 2-8°C	0,002	0,127	0,249	0,507	7 days at RT (18-25°C)	0,002	0,122	0,249	0,505	Δ A405 (7 days) ≤ 0.10
% PC	0	26	52	104																	
Fresh	0,001	0,126	0,251	0,509																	
7 days at 2-8°C	0,002	0,127	0,249	0,507																	
7 days at RT (18-25°C)	0,002	0,122	0,249	0,505																	

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Analytical data	Specifications																			
<p>f. <u>Automated method</u> <u>Method</u> : STAR</p> <table border="1" style="margin: 10px auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">% PC</th> <th style="text-align: center;">0</th> <th style="text-align: center;">25</th> <th style="text-align: center;">50</th> <th style="text-align: center;">100</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">A405</td> <td style="text-align: center;">0,001</td> <td style="text-align: center;">0,122</td> <td style="text-align: center;">0,241</td> <td style="text-align: center;">0,494</td> </tr> </tbody> </table> <p style="text-align: center; margin: 10px 0;">$R^2 = 1,000$</p> <table border="1" style="margin: 10px auto; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Control</th> <th style="text-align: center;">TV* % PC</th> <th style="text-align: center;">MV* % PC</th> </tr> </thead> <tbody> <tr> <td style="text-align: left;">Normal Control</td> <td style="text-align: center;">89</td> <td style="text-align: center;">93</td> </tr> <tr> <td style="text-align: left;">Abnormal Control</td> <td style="text-align: center;">38</td> <td style="text-align: center;">38</td> </tr> </tbody> </table> <p style="font-size: small; margin-top: 5px;">* TV= Target Value - MV= Measured Value</p>	% PC	0	25	50	100	A405	0,001	0,122	0,241	0,494	Control	TV* % PC	MV* % PC	Normal Control	89	93	Abnormal Control	38	38	<p style="text-align: center; margin: 20px 0;">$R^2 \geq 0.98$</p> <p style="margin-top: 20px;">MV = TV \pm 5% MV = TV \pm 8%</p>
% PC	0	25	50	100																
A405	0,001	0,122	0,241	0,494																
Control	TV* % PC	MV* % PC																		
Normal Control	89	93																		
Abnormal Control	38	38																		

Comments :



**PASSED
IN COMPLIANCE**

Date : 2017-08-30

QC Manager :

S. LECOURT