

ANALYSIS CERTIFICATE

BIOPHEN FVIII:C- #221402

Lot : F1700013

QC Release : 2017-02-24

Expiration date : 2019-06-29

Components	Volume	Exp. (months)	Lot #	Exp. date
R1 : Human Factor X	2 vials	30	F171H00013	2019-07-01
R2 : Activation Reagent	2 vials	30	F171H00013	2019-07-30
R3 : SXa-11 substrate	2 vials	30	F171H00013	2019-06-29
R4+ : Tris-BSA buffer	4 vials	30	F171H00013	2019-06-30

Beo

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Analytical data	Specifications																																								
1. Calibration curve																																									
High Range:																																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="3">VIII:C (%)</th> <th>A405</th> <th>A405</th> </tr> <tr> <th>STAR</th> <th>WB</th> <th></th> <th>W. Bath</th> <th>STAR</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>20</td> <td>0</td> <td>0,016</td> <td>0,07</td> </tr> <tr> <td>C/4</td> <td>50</td> <td>25</td> <td>0,157</td> <td>0,216</td> </tr> <tr> <td>C/2</td> <td>100</td> <td>50</td> <td>0,444</td> <td>0,451</td> </tr> <tr> <td>C</td> <td>160</td> <td>100</td> <td>1,146</td> <td>0,696</td> </tr> <tr> <td>2C</td> <td>190</td> <td>200</td> <td>2,224</td> <td>0,812</td> </tr> <tr> <td colspan="3">Linearity: R² =</td> <td>0,9935</td> <td>0,9987</td> </tr> </tbody> </table>	VIII:C (%)			A405	A405	STAR	WB		W. Bath	STAR	0	20	0	0,016	0,07	C/4	50	25	0,157	0,216	C/2	100	50	0,444	0,451	C	160	100	1,146	0,696	2C	190	200	2,224	0,812	Linearity: R ² =			0,9935	0,9987	<p style="text-align: center;">Water Bath: A405(200%) ≥ 1,60 ΔA405(100%-200%) ≥ 0.60</p> <p style="text-align: center;">R² ≥ 0.98</p>
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Control	TV* % VIII :C	MV* % VIII :C																																							
Normal Control	102	106																																							
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3. Detection threshold Method : CS5100																																									
High range: <2 % Low range: <1 %	<p>≤ 10%</p> <p>≤ 2%</p>																																								
4. Performances Method : CS5100																																									
Normal plasmas: N= 10 Mean= 68 % Range: 51 to 84 %	<p>N ≥ 10</p> <p>≥ 50 %</p> <p>About 50-150%</p>																																								
FVIII Deficient Plasma: <2 % VIII:C (high range) <1 % VIII:C (low range)	<p>< 10 %</p> <p>< 2 %</p>																																								
5. Stability of restored reagents Method : WB																																									
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">VIII:C (%)</th> <th>A405 Fresh</th> <th>A405 24H RT</th> <th>A405 72H 2-8°C</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>0</td> <td>0,031</td> <td>0,029</td> <td>0,029</td> </tr> <tr> <td>C/4</td> <td>25</td> <td>0,172</td> <td>0,159</td> <td>0,163</td> </tr> <tr> <td>C/2</td> <td>50</td> <td>0,466</td> <td>0,436</td> <td>0,446</td> </tr> <tr> <td>C</td> <td>100</td> <td>1,165</td> <td>1,117</td> <td>1,120</td> </tr> <tr> <td>2C</td> <td>200</td> <td>2,316</td> <td>2,227</td> <td>2,250</td> </tr> <tr> <td colspan="2">Linearity: R² =</td> <td>0,9964</td> <td>0,9958</td> <td>0,9966</td> </tr> </tbody> </table>	VIII:C (%)		A405 Fresh	A405 24H RT	A405 72H 2-8°C	0	0	0,031	0,029	0,029	C/4	25	0,172	0,159	0,163	C/2	50	0,466	0,436	0,446	C	100	1,165	1,117	1,120	2C	200	2,316	2,227	2,250	Linearity: R ² =		0,9964	0,9958	0,9966	<p>Δ A405 point C ≤ 15%</p> <p>Δ A405 point 2C ≤ 15%</p> <p>between fresh and 24h RT or 72H at 2-8°C</p>					
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Comments :



PASSED IN COMPLIANCE

Date : 2017-02-24

QC Manager : S.LECOURT

S. Lecourt