

ANALYSIS CERTIFICATE

BIOPHEN HEPARIN Anti Ila (2 stages) - #221025

Lot : F1600870

QC Release : 2016-11-09

Expiration date : 2019-02-19

Components	Qty	Exp. (months)	Int. Ref.	Lot #	Exp. date
R1 : Human Antithrombin	2 vials	30	F161200870	F161200870	2019-02-19
R2 : Human Thrombin	2 vials	30	F161200870	F161200870	2019-03-03
R3 : Thrombin substrate	2 vials	30	F161200870	F161200870	2019-02-24
R4 : Reaction buffer	4 vials	30	F161200870	F161200870	2019-03-02

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Analytical data	Specifications																					
<p>5. Assay reactivity</p> <p>a. <u>Manual method (concentration in the tested dilution)</u></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">UFH UI/ml</th> <th style="text-align: center;">0.0</th> <th style="text-align: center;">0.01</th> <th style="text-align: center;">0.02</th> <th style="text-align: center;">0.03</th> <th style="text-align: center;">0.04</th> <th style="text-align: center;">r^2</th> </tr> </thead> <tbody> <tr> <td>A405 UFH plasma</td> <td style="text-align: center;">1,836</td> <td style="text-align: center;">1,492</td> <td style="text-align: center;">1,233</td> <td style="text-align: center;">0,965</td> <td style="text-align: center;">0,867</td> <td style="text-align: center;">0,987</td> </tr> <tr> <td>A405 UFH purified</td> <td style="text-align: center;">1,774</td> <td style="text-align: center;">1,434</td> <td style="text-align: center;">1,151</td> <td style="text-align: center;">0,951</td> <td style="text-align: center;">0,830</td> <td style="text-align: center;">0,991</td> </tr> </tbody> </table>	UFH UI/ml	0.0	0.01	0.02	0.03	0.04	r^2	A405 UFH plasma	1,836	1,492	1,233	0,965	0,867	0,987	A405 UFH purified	1,774	1,434	1,151	0,951	0,830	0,991	<p>Δ A405 (0-0.04) \geq 0.70</p> <p>$r^2 \geq$ 0.98</p>
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<p>6. HNF Detection threshold (concentration in the tested dilution)</p> <p>In Plasma 0,0016 IU/ml</p> <p>In Purified solution 0,0012 IU/ml</p>	<p>\leq 0.002 IU/ml</p>
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<p>7. Stability of reconstituted reagents</p> <p>Reagents tested after 15 days at 2-8°C, or 4 days at RT (18-25°C) or Frozen/thawed</p> <p>A405 values</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">UFH IU/ml</th> <th style="text-align: center;">0.0</th> <th style="text-align: center;">0.01</th> <th style="text-align: center;">0.02</th> <th style="text-align: center;">0.03</th> <th style="text-align: center;">0.04</th> <th style="text-align: center;">r^2</th> </tr> </thead> <tbody> <tr> <td style="text-align: right;">(1)</td> <td style="text-align: center;">1,922</td> <td style="text-align: center;">1,670</td> <td style="text-align: center;">1,430</td> <td style="text-align: center;">1,200</td> <td style="text-align: center;">1,027</td> <td style="text-align: center;">0,984</td> </tr> <tr> <td style="text-align: right;">(2)</td> <td style="text-align: center;">1,996</td> <td style="text-align: center;">1,843</td> <td style="text-align: center;">1,548</td> <td style="text-align: center;">1,391</td> <td style="text-align: center;">1,211</td> <td style="text-align: center;">0,9847</td> </tr> <tr> <td style="text-align: right;">Freshly restored (3)</td> <td style="text-align: center;">1,706</td> <td style="text-align: center;">1,404</td> <td style="text-align: center;">1,120</td> <td style="text-align: center;">0,915</td> <td style="text-align: center;">0,742</td> <td style="text-align: center;">0,9996</td> </tr> <tr> <td style="text-align: right;">15 days at 2-8°C (3)</td> <td style="text-align: center;">1,551</td> <td style="text-align: center;">1,319</td> <td style="text-align: center;">1,062</td> <td style="text-align: center;">0,857</td> <td style="text-align: center;">0,668</td> <td style="text-align: center;">0,9949</td> </tr> <tr> <td style="text-align: right;">4 days at RT (1)</td> <td style="text-align: center;">1,759</td> <td style="text-align: center;">1,515</td> <td style="text-align: center;">1,275</td> <td style="text-align: center;">1,066</td> <td style="text-align: center;">0,888</td> <td style="text-align: center;">0,9957</td> </tr> <tr> <td style="text-align: right;">Frozen & Thawed (2)</td> <td style="text-align: center;">1,802</td> <td style="text-align: center;">1,553</td> <td style="text-align: center;">1,257</td> <td style="text-align: center;">1,110</td> <td style="text-align: center;">0,956</td> <td style="text-align: center;">0,9840</td> </tr> </tbody> </table>	UFH IU/ml	0.0	0.01	0.02	0.03	0.04	r^2	(1)	1,922	1,670	1,430	1,200	1,027	0,984	(2)	1,996	1,843	1,548	1,391	1,211	0,9847	Freshly restored (3)	1,706	1,404	1,120	0,915	0,742	0,9996	15 days at 2-8°C (3)	1,551	1,319	1,062	0,857	0,668	0,9949	4 days at RT (1)	1,759	1,515	1,275	1,066	0,888	0,9957	Frozen & Thawed (2)	1,802	1,553	1,257	1,110	0,956	0,9840	<p>$r^2 \geq$ 0.98</p> <p>Δ A405 (0 to 0.04 IU/ml) \geq 0.70</p> <p>Δ A405 (0 UI/mL) between series \leq 10%</p>
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<p>Comments :</p> <p>(1) Fresh vial for 4 days at RT</p> <p>(2) Fresh vial for frozen</p> <p>(3) Fresh for 15 days at 2-8°C</p> <p><i>Reedition of the CoA (QUCO 73198) due to layout discrepancy</i></p>	<p><input checked="" type="checkbox"/> PASSED IN COMPLIANCE</p>
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Date : 2017-04-06

QC Manager : S.LECOURT

