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CERTIFICATE OF ANALYSIS

**ZYMUPHEN
tPA Activity kit**

#521296

Lot : 151014C

Expiration date : 2018-03



ANALYSIS CERTIFICATE

tPA Activity kit #521296

Lot : 151014C

QC release : 19/10/2015

Expiration date : 2018-03

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) tPA pre-coated plate	12x8 wells	30	150929I	2018-03
tPA Calibrator	2 vials	30	150925D	2018-03
R1 Substrate	2 vials	30	151009B	2018-04
R2 Plasminogen reagent	2 vials	30	151006C	2018-04
Citrate-Phosphate Sample diluent	2x50	30	150928H	2018-03
Wash solution	1x50	42	141103K	2018-05
tPA Control I	2 vials	30	150925E	2018-03
tPA Control II	2 vials	30	150925F	2018-03
Stop solution (Citric acid 2%)	1x6	42	150917E	2019-03

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Analytical data	Specifications																																																			
1. <u>Reactivity</u> A405 for standard (C) : 2,060	> 1.60																																																			
2. <u>Calibrator Plasma</u> Concentration 2,02 IU/ml CV 6,6 %	[1.7 - 2.5 IU/ml] ≤ 10 %																																																			
3. <u>Blank value</u> A405 for sample diluent : 0,110 SD : 0,003	< 0.150 < 0.025																																																			
4. <u>Calibration curve</u> <table style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th style="width: 15%;">Conc.</th> <th style="width: 15%;">A405</th> <th style="width: 15%;">SD</th> <th style="width: 15%;">CV (%)</th> <th style="width: 10%;">N ≥10</th> <th style="width: 10%;">SD</th> <th style="width: 10%;">CV (%)</th> <th style="width: 20%;"></th> </tr> </thead> <tbody> <tr> <td>C</td> <td style="color: red; font-weight: bold;">2,060</td> <td style="color: red; font-weight: bold;">0,11</td> <td style="color: red; font-weight: bold;">5,6</td> <td style="color: red; font-weight: bold;">10</td> <td></td> <td></td> <td rowspan="6" style="vertical-align: middle; text-align: center;"> $\Delta OD_{(C-C/2)} \geq 0.60$ </td> </tr> <tr> <td>C/2</td> <td style="color: red; font-weight: bold;">1,112</td> <td style="color: red; font-weight: bold;">0,06</td> <td style="color: red; font-weight: bold;">5,1</td> <td style="color: red; font-weight: bold;">10</td> <td></td> <td></td> </tr> <tr> <td>C/4</td> <td style="color: red; font-weight: bold;">0,524</td> <td style="color: red; font-weight: bold;">0,03</td> <td style="color: red; font-weight: bold;">5,4</td> <td style="color: red; font-weight: bold;">10</td> <td></td> <td></td> </tr> <tr> <td>C/10</td> <td style="color: red; font-weight: bold;">0,252</td> <td style="color: red; font-weight: bold;">0,01</td> <td style="color: red; font-weight: bold;">5,5</td> <td style="color: red; font-weight: bold;">10</td> <td></td> <td></td> </tr> <tr> <td>C/20</td> <td style="color: red; font-weight: bold;">0,173</td> <td style="color: red; font-weight: bold;">0,01</td> <td style="color: red; font-weight: bold;">2,9</td> <td style="color: red; font-weight: bold;">10</td> <td style="color: red; font-weight: bold;"><0.05</td> <td></td> </tr> <tr> <td>0</td> <td style="color: red; font-weight: bold;">0,110</td> <td style="color: red; font-weight: bold;">0,003</td> <td style="color: red; font-weight: bold;">/</td> <td style="color: red; font-weight: bold;">10</td> <td style="color: red; font-weight: bold;"><0.025</td> <td></td> </tr> </tbody> </table>	Conc.	A405	SD	CV (%)	N ≥10	SD	CV (%)		C	2,060	0,11	5,6	10			$\Delta OD_{(C-C/2)} \geq 0.60$	C/2	1,112	0,06	5,1	10			C/4	0,524	0,03	5,4	10			C/10	0,252	0,01	5,5	10			C/20	0,173	0,01	2,9	10	<0.05		0	0,110	0,003	/	10	<0.025		
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5. <u>Linearity</u> R ² = 0,98	≥ 0.98																																																			
6. <u>Detection limit</u> Sensitivity <0,05 IU/ml	≤ 0.1IU/ml																																																			
7. <u>Controls</u> <table style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th style="width: 30%;"></th> <th style="width: 20%;">Target value IU/ml</th> <th style="width: 20%;">Measured value IU/ml</th> <th style="width: 30%;">Acceptance range</th> </tr> </thead> <tbody> <tr> <td>Control I</td> <td style="color: red; font-weight: bold;">3,31</td> <td style="color: red; font-weight: bold;">3,19</td> <td style="color: red; font-weight: bold;">2,81 to 3,81 IU/ml</td> </tr> <tr> <td>Control II</td> <td style="color: red; font-weight: bold;">1,40</td> <td style="color: red; font-weight: bold;">1,43</td> <td style="color: red; font-weight: bold;">1,12 to 1,68 IU/ml</td> </tr> </tbody> </table>		Target value IU/ml	Measured value IU/ml	Acceptance range	Control I	3,31	3,19	2,81 to 3,81 IU/ml	Control II	1,40	1,43	1,12 to 1,68 IU/ml																																								
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Date : 19.10.2015

QC Manager : S. LECOURT



ZYMUPHEN tPA Activity

Référence : 521296

Dosage fonctionnel du tPA par bio-immunoassay.

A usage de recherche *in vitro* exclusivement

ZYMUPHEN tPA Activity

521296

Functional assay of tPA by bio-immunoassay.

For *in vitro* research use only

FRANÇAIS

Lot : 151014C – Exp. : 2018-03

Calibreur Lot : **150925D**
Taux de tPA : 2.02 UI/ml

Control I Lot : **150925E**
Taux de tPA : 3.31 UI/ml
Intervalle de confiance : 2.81 – 3.81 UI/ml

Control II Lot : **150925F**
Taux de tPA : 1.40 UI/ml
Intervalle de confiance : 1.12 – 1.68 UI/ml

ENGLISH

Lot : 151014C – Exp. : 2018-03

Calibrator Lot : **150925D**
tPA concentration: 2.02 IU/ml

Control I Lot : **150925E**
tPA concentration: 3.31 IU/ml
Acceptance range: 2.81 – 3.81 IU/ml

Control II Lot : **150925F**
tPA concentration: 1.40 IU/ml
Acceptance range: 1.12 – 1.68 IU/ml


S. Lewis Smith
6/15/15