

**HYPHEN BioMed**  
ZAC Neuville Université  
155 rue d'Eragny  
95000 NEUVILLE SUR OISE  
FRANCE

Tel:+33.1.34.40.65.10  
Fax:+33.1.34.48.72.36  
[www.hyphen-biomed.com](http://www.hyphen-biomed.com)

# **CERTIFICATE OF ANALYSIS**

**ZYMUPHEN  
tPA Activity kit**

**#521296**

**Lot : F1600274**

**Expiration date : 2018-07-20**

*SE*

## ANALYSIS CERTIFICATE

tPA Activity kit #521296

Lot : F1600274

QC release : 2016-04-27

Expiration date : 2018-07-20

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) tPA pre-coated plate	12x8 wells	30	F1600387	2018-09-22
tPA Calibrator	2 vials	30	F1600154	2018-07-20
R1 Substrate	2 vials	30	F1600402	2018-09-28
R2 Plasminogen reagent	2 vials	30	F1600403	2018-09-28
Citrate-Phosphate Sample diluent	2x50	30	F1600388	2018-09-23
Wash solution	1x50	42	F1600026	2019-06-24
tPA Control I	2 vials	30	F1600155	2018-07-20
tPA Control II	2 vials	30	F1600156	2018-07-20
Stop solution (Citric acid 2%)	1x6	42	150917E	2019-03

# ANALYSIS CERTIFICATE

tPA Activity kit #521296

Lot : F1600274

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Analytical data	Specifications
<b>1. <u>Reactivity</u></b> A405 for standard (C) : <span style="float: right;">3,205</span>	> 1.60

<b>2. <u>Calibrator Plasma</u></b> Concentration <span style="float: right;">2,1 IU/ml</span> CV <span style="float: right;">1,2 %</span>	[1.7 - 2.5 IU/ml] ≤ 10 %
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<b>3. <u>Blank value</u></b> A405 for sample diluent : <span style="float: right;">0,094</span> SD : <span style="float: right;">0,002</span>	< 0.150 < 0.025
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<b>4. <u>Calibration curve</u></b> <table style="width: 100%; border-collapse: collapse;"> <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>3,205</td> <td>0,135</td> <td>4,2</td> <td>10</td> <td></td> <td>&lt;10</td> <td rowspan="5" style="text-align: center; vertical-align: middle;"> <math>\Delta OD_{(C-C/2)} \geq 0.60</math> </td> </tr> <tr> <td>C/2</td> <td>1,838</td> <td>0,08</td> <td>4,3</td> <td>10</td> <td></td> <td>&lt;10</td> </tr> <tr> <td>C/4</td> <td>0,958</td> <td>0,04</td> <td>4,6</td> <td>10</td> <td></td> <td>&lt;10</td> </tr> <tr> <td>C/10</td> <td>0,387</td> <td>0,01</td> <td>3,6</td> <td>10</td> <td></td> <td>&lt;10</td> </tr> <tr> <td>C/20</td> <td>0,225</td> <td>0,01</td> <td>3,0</td> <td>10</td> <td>&lt;0.05</td> <td></td> </tr> <tr> <td>0</td> <td>0,094</td> <td>0,002</td> <td>/</td> <td>10</td> <td>&lt;0.025</td> <td></td> <td></td> </tr> </tbody> </table>	Conc.	A405	SD	CV (%)	N ≥ 10	SD	CV (%)		C	3,205	0,135	4,2	10		<10	$\Delta OD_{(C-C/2)} \geq 0.60$	C/2	1,838	0,08	4,3	10		<10	C/4	0,958	0,04	4,6	10		<10	C/10	0,387	0,01	3,6	10		<10	C/20	0,225	0,01	3,0	10	<0.05		0	0,094	0,002	/	10	<0.025			
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<b>5. <u>Linearity</u></b> R <sup>2</sup> = <span style="float: right;">0,99</span>	≥ 0.98
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<b>6. <u>Detection limit</u></b> Sensitivity <span style="float: right;">&lt;0,05 IU/ml</span>	≤ 0.1IU/ml
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<u>Controls</u>	Target value IU/ml	Measured value IU/ml	Acceptance range
Control I	3,5	3,5	2,9 to 4,0 IU/ml
Control II	1,3	1,4	1,0 to 1,6 IU/ml

<u>Performances</u>	N	Measured value	Acceptance range
Normal Plasmas	N = 10	< 0,1	0 to 3IU/ml
tPA/PAI deficient plasma		<0,1	≤ 0.1IU/ml

<b>Comments :</b> R1 lot F1600402 and R2 lot F1600403 accepted under waiver (see NCI 1351)	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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Date : 27/04/2016

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

ENGLISH

**Lot : F1600274 – Exp. : 2018-07-20**

**Lot : F1600274 – Exp. : 2018-07-20**

Calibrateur Lot : F1600154 2.1 UI/ml  
Taux de tPA :  
  
Control I Lot : F1600155 3.5 UI/ml  
Taux de tPA :  
Intervalle de confiance : 2.9 – 4.0 UI/ml  
  
Control II Lot : F1600156 1.3 UI/ml  
Taux de tPA :  
Intervalle de confiance : 1.0 – 1.6 UI/ml

Calibrator Lot : F1600154 2.1 IU/ml  
tPA concentration:  
  
Control I Lot : F1600155 3.5 IU/ml  
tPA concentration:  
Acceptance range: 2.9 – 4.0 IU/ml  
  
Control II Lot : F1600156 1.3 IU/ml  
tPA concentration:  
Acceptance range: 1.0 – 1.6 IU/ml

*Alpina*

S. LECOURT  
29 AVR. 2016