

## ANALYSIS CERTIFICATE

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# CERTIFICATE OF ANALYSIS

## ZYMUPHEN MP-ACTIVITY

### #521096

**Lot : F1601058**

**Expiration date : 2019-03-02**



## ANALYSIS CERTIFICATE

**MP-Activity kit**

**Lot : F1601058**

**QC Release : 2016-11-03**

**Expiration date : 2019-03-02**

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
SA Annexin V pre-coated plate	12x8 wells	30	F1600974	2019-03-15
MP- Activity calibrator	2 vials	30	F1600717	2019-03-04
R1	2 vials	30	F1600713	2019-03-22
R2	2 vials	30	F1601059	2019-04-09
R3	2 vials	30	F1600715	2019-03-19
Sample Diluent (SD-MP)	2*50 ml	30	F1600735	2019-03-02
MP-Activity Control I High	1 vial	30	F1600718	2019-03-04
MP-Activity Control II Low	1 vial	30	F1600716	2019-03-04
Wash solution 10X (WS-MP)	1*50 ml	30	F1600923	2019-03-15
Citric Acid 2%	1x6 ml	42	F1600736	2020-03-02



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Analytical data	Specifications																																																	
<b>1. <u>Reactivity</u></b>  A405 for standard at 2.0nM : <span style="float: right;">2,110</span>	≥ 1.50																																																	
<b>2. <u>Calibrator Plasma</u></b> Concentration <span style="float: right;">2,6 nM</span> CV <span style="float: right;">5,5 %</span>	2.5 ± 0.5 nM ≤ 10 %																																																	
<b>3. <u>Blank value</u></b>  ΔA405 for Blank : <span style="float: right;">0,081</span> SD : <span style="float: right;">0,005</span>	<0.100 < 0.015																																																	
<b>4. <u>Calibration curve</u></b>  <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Conc.</th> <th>A405</th> <th>SD</th> <th>CV (%)</th> <th>N ≥10</th> <th>CV (%)</th> <th>OD</th> </tr> </thead> <tbody> <tr> <td>C</td> <td>2,640</td> <td>0,108</td> <td>4,1</td> <td>10</td> <td>&lt;10</td> <td>≤ 3.50</td> </tr> <tr> <td>C/2</td> <td>1,472</td> <td>0,051</td> <td>3,4</td> <td>10</td> <td>&lt;10</td> <td></td> </tr> <tr> <td>C/4</td> <td>0,804</td> <td>0,053</td> <td>6,6</td> <td>10</td> <td>&lt;10</td> <td></td> </tr> <tr> <td>C/10</td> <td>0,437</td> <td>0,026</td> <td>6,0</td> <td>10</td> <td>&lt;10</td> <td></td> </tr> <tr> <td>C/20</td> <td>0,287</td> <td>0,015</td> <td>5,3</td> <td>10</td> <td>&lt;10</td> <td></td> </tr> <tr> <td>0</td> <td>0,081</td> <td>0,005</td> <td>/</td> <td>14</td> <td>/</td> <td></td> </tr> </tbody> </table>	Conc.	A405	SD	CV (%)	N ≥10	CV (%)	OD	C	2,640	0,108	4,1	10	<10	≤ 3.50	C/2	1,472	0,051	3,4	10	<10		C/4	0,804	0,053	6,6	10	<10		C/10	0,437	0,026	6,0	10	<10		C/20	0,287	0,015	5,3	10	<10		0	0,081	0,005	/	14	/		
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<b>5. <u>Detection limit</u></b>  <div style="text-align: right;">Concentration nM &lt;0,1</div>	≤ 0.1 nM																																																	
<b>6. <u>Controls</u></b>  <table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th>Target value nM</th> <th>Measured value nM</th> <th>Acceptance range</th> </tr> </thead> <tbody> <tr> <td>Control I</td> <td>31</td> <td>34,6</td> <td>21,7 to 40,3 nM</td> </tr> <tr> <td>Control II</td> <td>16</td> <td>18,6</td> <td>10,4 to 21,6 nM</td> </tr> </tbody> </table>		Target value nM	Measured value nM	Acceptance range	Control I	31	34,6	21,7 to 40,3 nM	Control II	16	18,6	10,4 to 21,6 nM																																						
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<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>																																																	

Date : 2016-11-03

QC Manager : S. LECOURT





## ZYMUPHEN MP Activity

**REF** 521096

**Functional assay for the measurement of microparticles' procoagulant activity in plasma /**

**Dosage fonctionnel des microparticules plasmatiques par méthode colorimétrique**

*For in vitro research use only / A usage de recherche in vitro exclusivement*

**LOT** F1601058

 2019-03-02

<u>Values assigned / Valeurs cibles (*)</u>
<b>Calibrator / Calibrateur</b> LOT : F1600717 Concentration : <b>2.6 nM</b>
<b>Control / Contrôle CI</b> LOT : F1600718 Target value / Valeur cible : <b>31 nM</b> Acceptance range / Domaine d'acceptation : <b>[21.7 -40.3] nM</b>
<b>Control / Contrôle CII</b> LOT : F1600716 Target value / Valeur cible : <b>16 nM</b> Acceptance range / Domaine d'acceptation : <b>[10.4 -21.6] nM</b>

Standardization / Standardisation : NA

Approved Date / Date d'Approbation : 2016-11-03

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT

