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# **CERTIFICATE OF ANALYSIS**

**ZYMUTEST  
Anti-Annexin V IgG**

**#RK005A**

**Lot : F1500048    Expiration date : 2018-03-29**



## CERTIFICATE OF ANALYSIS

**Anti-Annexin V IgG Elisa Kit**

**Lot : F1500048**

**QC Release : 2016-01-07**

**Expiration date : 2018-03-29**

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Annexin V pre-coated plate	12x8 wells	30	F1500083	2018-06-03
Anti-Annexin V IgG calibrator	3 vials	30	151009G	2018-04
Negative control	3 vials	30	150105G	2018-07
Anti-(h)- IgG (Fc <sub>γ</sub> )-HRP immunoconjugate	3 vials	42	F1500076	2019-05-30
Autoimmunity Sample diluent	2x50	42	150825B	2019-02
Wash solution	1x50	42	151026C	2019-04
Conjugate diluent	1x25	42	140929I	2018-03
TMB	1x25		150914	2019-05
Sulfuric Acid 0,45M	1x6		150528A	2018-11

*SJB*

## CERTIFICATE OF ANALYSIS

Anti-Annexin V IgG Elisa Kit

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Analytical data	Specifications																																										
<b>1. <u>Reactivity</u></b>																																											
A450 for 50 AU/ml : <span style="float: right;">1,917</span>	≥ 1.50																																										
A450 for negative control : <span style="float: right;">0,216</span>	≤ 0.25																																										
Concentration: <span style="float: right;">3,2 AU/ml</span>	< 10 AU/ml																																										
A450 for Blank value : <span style="float: right;">0,058</span>	< 0.100																																										
<b>2. <u>Calibrator</u></b>																																											
Concentration <span style="float: right;">60 AU/ml</span>	≥ 50 AU/ml																																										
CV <span style="float: right;">1,7 %</span>	≤ 10 %																																										
<b>3. <u>Blank value</u></b>																																											
A450 for sample diluent : <span style="float: right;">0,058</span>	< 0.100																																										
SD : <span style="float: right;">0,006</span>	< 0.015																																										
<b>4. <u>Calibration curve</u></b>																																											
Curve Fitting : <span style="float: right;">Polynomial degree 2</span>																																											
<table style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: left;">Conc.</th> <th style="text-align: left;">OD</th> <th style="text-align: left;">SD</th> <th style="text-align: left;">CV (%)</th> <th style="text-align: left;">N</th> <th style="text-align: left;">CV (%)</th> </tr> </thead> <tbody> <tr> <td>60 AU/ml</td> <td>2,147</td> <td>0,05</td> <td>2,5</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>30 AU/ml</td> <td>1,313</td> <td>0,03</td> <td>2,6</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>15 AU/ml</td> <td>0,749</td> <td>0,02</td> <td>2,7</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>7,5 AU/ml</td> <td>0,423</td> <td>0,01</td> <td>3,1</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>3,75 AU/ml</td> <td>0,248</td> <td>0,006</td> <td>2,3</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>1,88 AU/ml</td> <td>0,152</td> <td>0,006</td> <td>4,2</td> <td>N = 6</td> <td>&lt;10</td> </tr> </tbody> </table>	Conc.	OD	SD	CV (%)	N	CV (%)	60 AU/ml	2,147	0,05	2,5	N = 6	<10	30 AU/ml	1,313	0,03	2,6	N = 6	<10	15 AU/ml	0,749	0,02	2,7	N = 6	<10	7,5 AU/ml	0,423	0,01	3,1	N = 6	<10	3,75 AU/ml	0,248	0,006	2,3	N = 6	<10	1,88 AU/ml	0,152	0,006	4,2	N = 6	<10	
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<b>5. <u>Detection threshold</u></b>																																											
Concentration																																											
<1 AU/ml	≤ 5 AU/ml																																										
<b>6. <u>Normal Plasma Tested</u></b>																																											
N= 32	M= 3,9 AU/ml																																										
SD= 1,8 AU/ml	N ≥ 24																																										
M+2SD= 7,5 AU/ml	M ≤ 10 AU/ml																																										
<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>																																										

Date : 07/01/2016

QC Manager :

S. LECOURT



## Zymutest Anti-Annexin V IgG / Anti-Annexine V IgG

**REF** RK005A

**Assay of auto-antibodies to Annexin V, IgG isotype, by ELISA**

**/ dosage des auto-anticorps Anti-Annexine V d'isotype IgG**

For in vitro use only / Utilisation in vitro exclusivement - For research use only / Uniquement à usage de recherche

**LOT** F1500048



2018-03-29

<u>Values assigned / Valeurs cibles (*)</u>
<b>Calibrator / Calibrateur</b> LOT : 151009G Concentration : 60 AU/mL / UA/mL
<b>Negative Control / Contrôle négatif</b> LOT : 150105G Acceptance range / Domaine d'acceptation : < 10 AU/mL / UA/mL

(\*) Standardization / Standardisation : NA

Note: Curve fitting suitable for RK005A using Magellan software (Tecan ®) : second-degree polynomial (\*\*), third-degree polynomial (\*\*), 4 parameters marquardt, 5 parameters marquardt, cubic spline, akima, and point to point / Les modes d'interpolation adaptés pour RK005A sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 2 (\*\*), polynôme de degré 3 (\*\*), 4 paramètres marquardt, 5 paramètres marquardt, spline cubique, akima, et point par point.

(\*\*) Best fit suggested / Mode d'interpolation à favoriser

Approved Date / Date d'Approbation : 07/01/2016

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT