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# **CERTIFICATE OF ANALYSIS**

**ZYMUTEST  
Anti-Annexin V IgG**

**#RK005A**

**Lot : F1600636**

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



## CERTIFICATE OF ANALYSIS

**Anti-Annexin V IgG Elisa Kit**

**Lot : F1600636**

**QC Release : 2016-10-11**

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

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Annexin V pre-coated plate	12x8 wells	30	F1600637	2019-03-08
Anti-Annexin V IgG calibrator	3 vials	30	F1600925	2019-03-03
Negative control	3 vials	30	F1500035	2019-05-21
Anti-(h)- IgG (Fc $\gamma$ )-HRP immunoconjugate	3 vials	42	F1600640	2020-03-05
Autoimmunity Sample diluent	2x50	42	F1600571	2019-11-06
Wash solution	1x50	42	F1600690	2019-12-18
Conjugate diluent	1x25	42	150914G	2019-03
TMB	1x25		150915D02	2019-09-30
Sulfuric Acid 0,45M	1x6		F1600740	2019-12-17

*OS*

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**Anti-Annexin V IgG Elisa Kit**

**Lot : F1600636**

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Analytical data	Specifications																																										
<b>1. <u>Reactivity</u></b>																																											
A450 for 50 AU/ml : <span style="float: right;">2,154</span>	≥ 1.50																																										
A450 for negative control : <span style="float: right;">0,218</span>	≤ 0.25																																										
Concentration: <span style="float: right;">2,7 AU/ml</span>	< 10 AU/ml																																										
A450 for Blank value : <span style="float: right;">0,045</span>	< 0.100																																										
<b>2. <u>Calibrator</u></b>																																											
Concentration <span style="float: right;">58 AU/ml</span>	≥ 50 AU/ml																																										
CV <span style="float: right;">2,8 %</span>	≤ 10 %																																										
<b>3. <u>Blank value</u></b>																																											
A450 for sample diluent : <span style="float: right;">0,045</span>	< 0.100																																										
SD : <span style="float: right;">0,008</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="width: 15%;">Conc.</th> <th style="width: 15%;">OD</th> <th style="width: 15%;">SD</th> <th style="width: 15%;">CV (%)</th> <th style="width: 15%;">N</th> <th style="width: 15%;">CV (%)</th> </tr> </thead> <tbody> <tr> <td>58 AU/ml</td> <td>2,292</td> <td>0,100</td> <td>4,4</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>29 AU/ml</td> <td>1,528</td> <td>0,07</td> <td>4,3</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>14,5 AU/ml</td> <td>0,909</td> <td>0,04</td> <td>4,3</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>7,3 AU/ml</td> <td>0,495</td> <td>0,01</td> <td>2,8</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>3,6 AU/ml</td> <td>0,272</td> <td>0,02</td> <td>6,7</td> <td>N = 6</td> <td>&lt;10</td> </tr> <tr> <td>1,8 AU/ml</td> <td>0,168</td> <td>0,01</td> <td>6,3</td> <td>N = 6</td> <td>&lt;10</td> </tr> </tbody> </table>	Conc.	OD	SD	CV (%)	N	CV (%)	58 AU/ml	2,292	0,100	4,4	N = 6	<10	29 AU/ml	1,528	0,07	4,3	N = 6	<10	14,5 AU/ml	0,909	0,04	4,3	N = 6	<10	7,3 AU/ml	0,495	0,01	2,8	N = 6	<10	3,6 AU/ml	0,272	0,02	6,7	N = 6	<10	1,8 AU/ml	0,168	0,01	6,3	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= 3,6 AU/ml																																										
SD= 2,2 AU/ml	N ≥ 24																																										
M+2SD= 8 AU/ml	M ≤ 10 AU/ml																																										
<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>																																										

**Date : 2016-11-10**

**QC Manager :**

**S.LECOURT**





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ENGLISH / FRANÇAIS

## 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** F1600636



2019-03-03

<u>Values assigned / Valeurs cibles (*)</u>
<b>Calibrator / Calibrateur LOT : F1600925</b> <b>Concentration : 58 AU/mL / UA/mL</b>
<b>Negative Control / Contrôle négatif LOT : F1500035</b> <b>Acceptance range / Domaine d'acceptation : &lt; 10 AU/mL / UA/mL</b>

(\*) 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* : 2016-11-10

Quality Control Manager / *Responsable Contrôle Qualité* : S.LECOURT