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CERTIFICATE OF ANALYSIS

**ZYMUTEST
Anti-Annexin V IgM**

#RK005B

Lot : F1600994

Expiration date : 2019-03-03

905

CERTIFICATE OF ANALYSIS

Anti-Annexin V IgM Elisa Kit

Lot : F1600994

QC Release : 2017-02-07

Expiration date : 2019-03-03

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Annexin V pre-coated plate	12x8 wells	30	F1700105	2019-07-12
Anti-Annexin V IgM calibrator	3 vials	30	F1600924	2019-03-03
Negative control	3 vials	30	F1600728	2019-12-20
Anti-(h)- IgM (μ)-HRP immunoconjugate	3 vials	42	F1500077	2019-05-30
Autoimmunity Sample diluent	2x50	42	F1601236	2020-05-11
Wash solution	1x50	42	F1600780	2020-01-21
Conjugate diluent	1x25	42	F1600708	2019-12-11
TMB	1x25		150915D02	2019-09-30
Sulfuric Acid 0,45M	1x6		F1600740	2019-12-17

S.03

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Analytical data	Specifications																																										
1. <u>Reactivity</u>																																											
A450 for 75 AU/ml : 1,369	≥ 1.30																																										
A450 for negative control : 0,061	≤ 0.25																																										
Concentration: 2,2 AU/ml	< 10 AU/ml																																										
A450 for Blank value : 0,005	< 0.100																																										
2. <u>Calibrator</u>																																											
Concentration 130 AU/ml	≥ 75 AU/ml																																										
CV 2,7 %	≤ 10 %																																										
3. <u>Blank value</u>																																											
A450 for sample diluent : 0,005	< 0.100																																										
SD : 0,005	< 0.015																																										
4. <u>Calibration curve</u>																																											
Curve Fitting : polynom 2																																											
<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>4,1 AU/ml</td> <td>0,103</td> <td>0,007</td> <td>6,6</td> <td>N = 6</td> <td><10</td> </tr> <tr> <td>8,1 AU/ml</td> <td>0,197</td> <td>0,010</td> <td>5,1</td> <td>N = 6</td> <td><10</td> </tr> <tr> <td>16,3 AU/ml</td> <td>0,374</td> <td>0,008</td> <td>2,0</td> <td>N = 6</td> <td><10</td> </tr> <tr> <td>32,5 AU/ml</td> <td>0,713</td> <td>0,026</td> <td>3,6</td> <td>N = 6</td> <td><10</td> </tr> <tr> <td>65 AU/ml</td> <td>1,230</td> <td>0,013</td> <td>1,1</td> <td>N = 6</td> <td><10</td> </tr> <tr> <td>130 AU/ml</td> <td>1,824</td> <td>0,032</td> <td>1,8</td> <td>N = 6</td> <td><10</td> </tr> </tbody> </table>	Conc.	OD	SD	CV (%)	N	CV (%)	4,1 AU/ml	0,103	0,007	6,6	N = 6	<10	8,1 AU/ml	0,197	0,010	5,1	N = 6	<10	16,3 AU/ml	0,374	0,008	2,0	N = 6	<10	32,5 AU/ml	0,713	0,026	3,6	N = 6	<10	65 AU/ml	1,230	0,013	1,1	N = 6	<10	130 AU/ml	1,824	0,032	1,8	N = 6	<10	
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5. <u>Detection threshold</u>																																											
Sensitivity	Concentration <1 AU/ml																																										
	≤ 5 AU/ml																																										
6. <u>Normal Plasma Tested</u>																																											
N= 32	M= 3,1 AU/ml																																										
M+2SD= 6,5	SD= 1,7 AU/ml																																										
	N ≥ 24 M ≤ 10 AU/ml																																										
Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE																																										

Date : 2017-02-07

QC Manager :

S.LECOURT



Zymutest Anti-Annexin V IgM / Anti-Annexine V IgM

REF RK005B

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

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

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

LOT F1600994



2019-03-03

Values assigned / Valeurs cibles (*)

Calibrator / Calibrateur LOT : F1600924

Concentration : 130 AU/mL / UA/mL

Negative Control / Contrôle négatif LOT : F1600728

Acceptance range / Domaine d'acceptation : < 10 AU/mL / UA/mL

(*) Standardization / Standardisation : NA

Note: Curve fitting suitable for RK005B using Magellan software (Tecan ®) : second-degree polynomial (**), third-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, cubic spline, akima, and point to point / Les modes d'interpolation adaptés pour RK005B sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 2 (**), polynôme de degré 3 (**), 4 paramètres, 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 : 2017-02-07

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT