



HYPHEN BioMed
155 rue d'Eragny
95000 Neuville-sur-Oise
France

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST Anti Annexin V IgM

Product Code : RK005B

Lot No. : F1801311

Expiration date : 2020-12-31

Components	Quantity	Lot	Expiration Date
Annexin V pre-coated plate	12x8 wells	F1801301	2021-03-06
Anti-Annexin V IgM Standard	3 vials	F1801283	2021-03-09
Negative Control	3 vials	F1801230	2022-02-07
Anti-(h)-IgM μ HRP immunoconjugate	3 vials	F1801314	2022-03-10
Autoimmunity Sample diluent	2x50 ml	F1801362	2022-03-15
Wash solution	1x50 ml	F1800109	2021-07-13
Conjugate diluent	1x25 ml	F1700906	2021-01-27
TMB	1x25 ml	161208D01	2020-12-31
Sulfuric Acid 0,45M	1x6 ml	F1800049	2021-06-29

Analytical Data	Specification	Result
Reactivity	A450 for 75 AU/ml \geq 1.30	1.49
Calibration Curve and Negative Control	Negative Control measured within acceptance range	Negative control measured within acceptance range
Blank	< 0.100	0.016
Normal Plasma	\leq 10 AU/ml	< 2.4 AU/ml
Detection threshold	\leq 5 AU/ml	< 1.07 AU/ml

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Date of Approval : 2018-10-11

Quality Control Manager :

A.M VISSAC





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 F1801311



2020-12-31

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1801283 Concentration : 101 AU/mL / UA/mL
Negative Control / Contrôle négatif LOT : F1801230 Acceptance range / Domaine d'acceptation : < 10 AU/mL / UA/mL

(*) Standardization / Standardisation : **N/A**

Note: Curve fitting suitable for RK005B 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 RK005B sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 2 (**), polynôme de degré 3 (**), 4 paramètres, 5 paramètres marquardt, spline cubique, akima, et point par point.

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

Approved Date / Date d'Approbation : 2018-10-11

Quality Control Manager / Responsable Contrôle Qualité : A.M VISSAC