



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. : FD1275
Expiration date : 2026-12-11

Components	Quantity	Lot	Expiration Date
Annexin V pre-coated plate	12x8 wells	FD1251	2026-12-11
Anti-Annexin V IgM Standard	3 vials	FD1286	2026-12-21
Negative Control	3 vials	FD1252	2027-12-10
Anti-(h)-IgM μ HRP immunoconjugate	3 vials	FD1359	2027-12-23
Autoimmunity Sample diluent	2x50 ml	FD1282	2027-12-13
Wash solution	1x50 ml	FD0322	2027-07-26
Conjugate diluent	1x25 ml	FD0391	2027-08-02
TMB	1x25 ml	221201D01R	2027-10-31
Sulfuric Acid 0,45M	1x6 ml	FD0462	2027-08-09

Analytical Data	Specification	Result
Reactivity	A450 for 75 AU/ml \geq 1.20	1.43
Calibration Curve and Negative Control	Negative Control measured within acceptance range	PASS
Blank	< 0.100	0.008
Normal Plasma	\leq 10 AU/ml	< 2 AU/ml
Detection threshold	\leq 5 AU/ml	< 1 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 : **Quality Control Approval** Quality Control Manager :

22 JUL. 2024
S. LECOURT
