



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. : FB1144

Expiration date : 2024-12-27

Components	Quantity	Lot	Expiration Date
Annexin V pre-coated plate	12x8 wells	FB1140	2024-12-27
Anti-Annexin V IgM Standard	3 vials	FB1185	2025-01-06
Negative Control	3 vials	FA2224	2025-05-13
Anti-(h)-IgM μ HRP immunoconjugate	3 vials	FB1524	2026-03-02
Autoimmunity Sample diluent	2x50 ml	FB0727	2025-10-06
Wash solution	1x50 ml	FB0867	2025-11-03
Conjugate diluent	1x25 ml	FA1521	2025-02-24
TMB	1x25 ml	210302D01	2025-03-30
Sulfuric Acid 0,45M	1x6 ml	FA1514	2025-02-17

Analytical Data	Specification	Result
Reactivity	A450 for 75 AU/ml ≥ 1.20	1.66
Calibration Curve and Negative Control	Negative Control measured within acceptance range	PASS
Blank	< 0.100	0.011
Normal Plasma	≤ 10 AU/ml	< 10 AU/mL
Detection threshold	≤ 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 : 2022-09-29

Quality Control Manager : S.LECOURT