



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

CERTIFICATE OF ANALYSIS	
Product Description : ZYMUTEST HIA IgG Monostrip	
Product Code :	RK041A
Lot No. :	FD1267
Expiration date :	2027-02-12

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	FD1707	2027-02-19
HIA IgG Positive Control	4 vials	FD1856	2027-03-12
Negative Control	4 vials	FD1268	2027-12-10
Anti-(h)-IgG HRP immunoconjugate	4 vials	FD1858	2028-03-09
HIA Sample diluent	2x12 ml	FD1662	2027-02-12
Wash solution	2x12 ml	FD1331	2027-12-22
Cell Lysate	4 vials	FD1807	2027-03-08
Conjugate diluent	1x10 ml	FD1443	2028-01-03
TMB	1x10 ml	230801D02	2027-08-31
Sulfuric Acid 0,45M	1x3 ml	FD1507	2028-01-12

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control ≥ 1.00 A450 for Negative Control ≤ 0.25	1.747 0.049
Pathological Plasmas	A450 ≥ 0.300	PASS
Blank	< 0.100	0.023
Normal Plasma	M + 2SD ≤ 0.30	0.266

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

Quality Control Approval
Date of Approval : 08 OCT. 2024
Quality Control Manager : S. LECOURT

