



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. : FD0343

Expiration date : 2026-08-14

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	FD0436	2026-08-21
HIA IgG Positive Control	4 vials	FD0548	2026-09-04
Negative Control	4 vials	FD0351	2027-07-26
Anti-(h)-IgG HRP immunoconjugate	4 vials	FD0645	2027-09-06
HIA Sample diluent	2x12 ml	FD0438	2026-08-14
Wash solution	2x12 ml	FD0328	2027-07-26
Cell Lysate	4 vials	FD0466	2026-08-24
Conjugate diluent	1x10 ml	FD0389	2027-08-02
TMB	1x10 ml	230801D02	2027-08-31
Sulfuric Acid 0,45M	1x3 ml	FD0440	2027-08-09

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control ≥ 1.00 A450 for Negative Control ≤ 0.25	1.612 0.032
Pathological Plasmas	A450 ≥ 0.300	PASS
Blank	< 0.100	0.014
Normal Plasma	$M + 2SD \leq 0.30$	0.168

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 :

23 AVR. 2024

S. LECOURT

