



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. : FA2025
Expiration date : 2024-01-19

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	FA1524	2024-03-08
HIA IgG Positive Control	4 vials	FA1915	2024-03-29
Negative Control	4 vials	FA2026	2025-04-15
Anti-(h)-IgG HRP immunoconjugate	4 vials	FA1532	2025-03-20
HIA Sample diluent	2x12 ml	FA1508	2024-01-19
Wash solution	2x12 ml	FA1510	2025-02-10
Cell Lysate	4 vials	FA1530	2024-03-17
Conjugate diluent	1x10 ml	FA1520	2025-02-24
TMB	1x10 ml	210506D01	2025-05-31
Sulfuric Acid 0,45M	1x3 ml	FA1513	2025-02-17

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control ≥ 1.00 A450 for Negative Control ≤ 0.25	1.530 0.048
Pathological Plasmas	A450 ≥ 0.300	PASS
Blank	< 0.100	0.013
Normal Plasma	M + 2SD ≤ 0.30	0.097

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

Date of Approval : 2021-11-15

Quality Control Manager : S.LECOURT