



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

## CERTIFICATE OF ANALYSIS

**Product Description:** ZYMUTEST HIA IgG,A,M Monostrip  
**Product Code:** RK041D  
**Lot No.:** FA1279  
**Expiration date:** 2023-09-23

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	FA1284	2023-12-23
HIA IgG,A,M Positive Control	4 vials	FA1301	2024-01-26
Negative Control	4 vials	FA1477	2025-01-20
Anti-(h) IgA - Anti IgG - Anti IgM HRP immunoconjugate	4 vials	FA1287	2025-01-16
HIA Sample diluent	2x12 ml	FA0735	2023-09-23
Wash solution	2x12 ml	FA0932	2024-10-14
Cell Lysate	4 vials	FA1291	2024-01-13
Conjugate diluent	1x10 ml	FA1122	2024-11-18
TMB	1x10 ml	210506D01	2025-05-31
Sulfuric Acid 0,45M	1x3 ml	FA1282	2024-12-24

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control $\geq 1.00$ A450 for Negative Control $\leq 0.30$	1.64 0.085
Pathological Plasmas	A450 $\geq 0.500$	PASS
Blank	$< 0.100$	0.030
Normal Plasma	$M + 2SD \leq 0.50$	0.185

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

Date of Approval: 2021-08-24

Quality Control Manager: S.LECOURT

