



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.:** FB0419  
**Expiration date:** 2024-09-06

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	FB0514	2024-09-06
HIA IgG Positive Control	4 vials	FB0687	2024-10-07
Negative Control	4 vials	FB0599	2025-09-15
Anti-(h)-IgG HRP immunoconjugate	4 vials	FB0641	2025-09-25
HIA Sample diluent	2x12 ml	FB0566	2024-09-13
Wash solution	2x12 ml	FB0446	2025-08-18
Cell Lysate	4 vials	FB0601	2024-09-23
Conjugate diluent	1x10 ml	FB0596	2025-09-15
TMB	1x10 ml	210604D03	2025-06-30
Sulfuric Acid 0,45M	1x3 ml	FB0507	2025-09-01

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control $\geq 1.00$ A450 for Negative Control $\leq 0.25$	1.623 0.053
Pathological Plasmas	A450 $\geq 0.300$	PASS
Blank	$< 0.100$	0.013
Normal Plasma	$M + 2SD \leq 0.30$	0.27

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

Date of Approval: 2022-05-19

Quality Control Manager: S.LECOURT

