



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. :** F2001672

**Expiration date :** 2023-05-30

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	FA0338	2023-07-21
HIA IgG Positive Control	4 vials	FA0404	2023-07-31
Negative Control	4 vials	FA0405	2024-07-25
Anti-(h)-IgG HRP immunoconjugate	4 vials	FA0336	2024-07-18
HIA Sample diluent	2x12 ml	FA0222	2023-06-30
Wash solution	2x12 ml	FA0258	2024-07-03
Cell Lysate	4 vials	FA0295	2023-07-14
Conjugate diluent	1x10 ml	F2000349	2023-09-26
TMB	1x10 ml	190506D02	2023-05-30
Sulfuric Acid 0,45M	1x3 ml	F2001719	2024-06-19

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control $\geq 1.00$ A450 for Negative Control $\leq 0.25$	1.45 0.03
Pathological Plasmas	A450 $\geq 0.300$	PASS
Blank	$< 0.100$	0.007
Normal Plasma	$M + 2SD \leq 0.30$	0.09

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

Date of Approval : 2021-03-01

Quality Control Manager : S.LECOURT