



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. : F2000100
Expiration date : 2022-07-22

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	F2000168	2022-07-22
HIA IgG Positive Control	4 vials	F2000263	2022-08-09
Negative Control	4 vials	F2000173	2023-07-21
Anti-(h)-IgG HRP immunoconjugate	4 vials	F2000176	2023-07-31
HIA Sample diluent	2x12 ml	F2000239	2022-07-29
Wash solution	2x12 ml	F2000288	2023-08-14
Cell Lysate	4 vials	F2000169	2022-07-22
Conjugate diluent	1x10 ml	F2000349	2023-09-26
TMB	1x10 ml	190506D02	2023-05-30
Sulfuric Acid 0,45M	1x3 ml	F2000260	2023-07-31

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control ≥ 1.00 A450 for Negative Control ≤ 0.25	1.70 0.04
Pathological Plasmas	A450 ≥ 0.300	> 0.8
Blank	< 0.100	0.01
Normal Plasma	M + 2SD ≤ 0.30	0.11

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

Date of Approval: 2020-04-28

Quality Control Manager: S. LECOURT

