



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.: F2001434

Expiration date: 2023-04-21

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	F2001460	2023-04-21
HIA IgG,A,M Positive Control	4 vials	F2001558	2023-05-15
Negative Control	4 vials	F2000173	2023-07-21
Anti-(h) IgA - Anti IgG - Anti IgM HRP immunoconjugate	4 vials	F2001502	2024-05-02
HIA Sample diluent	2x12 ml	F2001491	2023-04-28
Wash solution	2x12 ml	F2000288	2023-08-14
Cell Lysate	4 vials	F2001501	2023-05-05
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 ≤ 0.30	1.91 0.09
Pathological Plasmas	A450 ≥ 0.500	PASS
Blank	< 0.100	0.01
Normal Plasma	M + 2SD ≤ 0.50	0.16

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

Date of Approval: 2020-12-15

Quality Control Manager: S. LECOURT