



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

CERTIFICATE OF ANALYSIS
Product Description: ZYMUTEST HIA IgG,A,M

Product Code: RK040D

Lot No.: F2000762

Expiration date: 2022-12-02

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	12x8 wells	F2000820	2022-12-02
HIA Ig G,A,M Positive Control	3 vials	F2000880	2022-12-12
Negative Control	3 vials	F2000171	2023-07-21
Anti (h) IgG - Anti IgA - Anti IgM HRP immunoconjugate	3 vials	F2000879	2023-12-04
HIA Sample diluent	2x50 ml	F2000938	2022-12-16
Wash solution	1x50 ml	F2000037	2023-06-27
Cell Lysate	3 vials	F2000819	2022-12-06
Conjugate diluent	1x25 ml	F2000351	2023-09-26
TMB	1x25 ml	190705D01	2023-07-30
Sulfuric Acid 0,45M	1x6 ml	F1903262	2023-05-29

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control ≥ 1.00 A450 for Negative Control ≤ 0.30	1.73 0.09
Pathological Plasmas	A450 ≥ 0.500	> 0.500
Blank	< 0.100	0.020
Normal Plasma	M + 2SD ≤ 0.50	0.19

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

Date of Approval: 2020-07-16

Quality Control Manager: S. LECOURT