



A Company of Sysmex Group



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. : FA0474

Expiration date : 2023-09-16

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	12x8 wells	FA0477	2023-09-16
HIA Ig G,A,M Positive Control	3 vials	FA0478	2023-10-02
Negative Control	3 vials	F2000655	2023-10-27
Anti (h) IgG - Anti IgA - Anti IgM HRP immunoconjugate	3 vials	FA0476	2024-09-19
HIA Sample diluent	2x50 ml	FA0480	2023-09-23
Wash solution	1x50 ml	FA0256	2024-07-03
Cell Lysate	3 vials	FA0688	2023-09-18
Conjugate diluent	1x25 ml	F2001563	2024-05-08
TMB	1x25 ml	200204D01	2024-02-28
Sulfuric Acid 0,45M	1x6 ml	F2001720	2024-06-19

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control ≥ 1.00 A450 for Negative Control ≤ 0.30	1.99 0.08
Pathological Plasmas	A450 ≥ 0.500	PASS
Blank	< 0.100	0.017
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 : 2021-05-12

Quality Control Manager : S.LECOURT