HYPHEN BioMed
A Company of Sysmex Group

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. : FF0131 / FF0481

Expiration date : 2028-07-28

Components	Quantity	Lot	Expiration Date
Heparin pre-coated plate	4 (x8 wells)	FF0763	2028-09-08
HIA IgG Positive Control	4 vials	FF0961	2028-09-30
Negative Control	4 vials	FF0527	2029-08-10
Anti-(h)-IgG HRP immunoconjugate	4 vials	FF1061	2029-10-17
HIA Sample diluent	2x12 ml	FF0458	2028-07-28
Wash solution	2x12 ml	FF0722	2029-08-27
Cell Lysate	4 vials	FF0847	2028-09-18
Conjugate diluent	1x10 ml	FF0770	2029-09-04
TMB	1x10 ml	241004D02	2028-10-30
Sulfuric Acid 0,45M	1x3 ml	FF0724	2029-08-27

Analytical Data	Specification	Result
Reactivity	A450 for Positive Control ≥ 1.00 A450 for Negative Control ≤ 0.25	1.716 0.037
Pathological Plasmas	A450 ≥ 0.300	PASS
Blank	< 0.100	0.021
Normal Plasma	M + 2SD ≤ 0.30	0.128

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

Date of Approval : **Quality Control Approval** Quality Control Manager :

27 MAI 2026

p/o S.MONEUS