



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST (h) PAI-1 Antigen

Product Code : RK012A

Lot No. : FE2303

Expiration date : 2028-05-01

Components	Quantity	Lot	Expiration Date
Anti-(h)-PAI-1 pre-coated plate	12x8 wells	FE2328	2028-09-25
(h) PAI-1 standard	3 vials	FE2296	2028-09-18
(h) PAI-1 Control I	1 vial	FE2298	2028-09-18
(h) PAI-1 Control II	1 vial	FE2297	2028-09-18
Anti-(h)-PAI-1 HRP immunoconjugate	3 vials	FE2587	2028-11-02
F-Sample diluent	2x50 ml	FD2397	2028-05-08
Wash solution	1x50 ml	FE0011	2028-06-15
Conjugate diluent	1x25 ml	FD2352	2028-05-01
TMB	1x25 ml	250104D01	2029-01-31
Sulfuric Acid 0,45M	1x6 ml	FE0017	2028-06-19

Analytical Data	Specification	Result
Reactivity	A450 for 8 ng/ml $\geq$ 1.40	1.545
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	PASS
Blank	< 0.100	0.014
Detection threshold	≤ 0.5 ng/ml	< 0.1 ng / mL

Calibration Curve for information

Conc.	C	C/2	C/4	C/10	C/20
OD	1.780	1.091	0.632	0.308	0.164

MV = Measured value

	Acceptance Range	MV
CI	[29.6 - 40.0]	37.0
CII	[11.2 - 16.7]	13.7

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

Date of Approval :

10.06.2025

Quality Control Manager :

Claire DUNOIS
Dir. Etudes Clin. & Val.

