



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. : F1901189

Expiration date : 2022-12-06

Components	Quantity	Lot	Expiration Date
Anti-(h)-PAI-1 pre-coated plate	12x8 wells	F1903069	2023-04-10
(h) PAI-1 standard	3 vials	F1903060	2023-04-12
(h) PAI-1 Control I	1 vial	F1903061	2023-04-12
(h) PAI-1 Control II	1 vial	F1903063	2023-04-12
Anti-(h)-PAI-1 HRP immunoconjugate	3 vials	F1903086	2023-04-17
F-Sample diluent	2x50 ml	F1903028	2023-04-05
Wash solution	1x50 ml	F1900767	2022-12-06
Conjugate diluent	1x25 ml	F1900898	2022-12-27
TMB	1x25 ml	190705D01	2023-07-30
Sulfuric Acid 0,45M	1x6 ml	F1900840	2023-12-23

Analytical Data	Specification	Result
Reactivity	A450 for 8 ng/ml \geq 1.40	1,81
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls are in acceptance ranges
Blank	< 0.100	0.002
Detection threshold	\leq 0.5 ng/ml	< 0.1 ng/ml

Calibration Curve for information

Conc.	C	C/2	C/4	C/10	C/20
OD	2.17	1.45	0.85	0.38	0.20

MV = Measured value

	Acceptance Range	MV
CI	[30 - 40]	34
CII	[14 - 22]	16

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

Date of Approval: 2019-12-02

Quality Control Manager: S. LECOURT



Zymutest PAI-1 Antigen / PAI-1 Antigène

REF RK012A

Assay of PAI-1 Antigen by ELISA / Dosage ELISA du PAI-1 Antigène

For in vitro use only / Utilisation in vitro exclusivement

LOT F1901189



2022-12-06

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1903060 Concentration : 11.3 ng/mL
Control / Contrôle CI LOT : F1903061 Target value / Valeur cible : 35 ng/mL Acceptance range / Domaine d'acceptation : [30 - 40] ng/mL
Control / Contrôle CII LOT : F1903063 Target value / Valeur cible : 18 ng/mL Acceptance range / Domaine d'acceptation : [14 - 22] ng/mL

(*) Standardization / Standardisation : **NA**

Note: Curve fitting suitable for RK012A using Magellan software (Tecan ®) : second-degree polynomial (**), third-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, cubic spline, akima, and point to point / Les modes d'interpolation adaptés pour RK012A sur le logiciel Magellan (Tecan ®) sont : polynôme de degré 2 (**), polynôme de degré 3 (**), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt, spline cubique, akima, et point par point.

(**) Best fit suggested / Mode d'interpolation à favoriser

Approved Date / Date d'Approbation : 2019-12-02

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT