



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

CERTIFICATE OF ANALYSIS

Product Description : ZYMUTEST PAI-1 Activity

Product Code : RK019A

Lot No. : F1801673

Expiration date : 2021-11-22

Components	Quantity	Lot	Expiration Date
tPA pre-coated plate	12x8 wells	F1900392	2022-09-07
(h) PAI-1 standard	3 vials	F1900425	2022-09-12
(h) PAI-1 Control I	1 vial	F1900367	2022-08-29
(h) PAI-1 Control II	1 vial	F1900368	2022-08-29
Anti-(h)-PAI-1 HRP immunoconjugate	3 vials	F1900433	2022-09-15
F-Sample diluent	2x50 ml	F1801598	2022-05-16
Wash solution	1x50 ml	F1800925	2021-11-22
Conjugate diluent	1x25 ml	F1900006	2022-06-21
TMB	1x25 ml	190103D02	2023-01-31
Sulfuric Acid 0,45M	1x6 ml	F1900172	2022-07-19

Analytical Data	Specification	Result
Reactivity	A450 for 8 ng/ml \geq 1.00	1.789
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls measured values within acceptance ranges
Blank	< 0.100	0.010
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	2.023	1.231	0.647	0.256	0.135

	Acceptance Range	MV
CI	[5.9 - 7.9] ng/mL	6.4
CII	[1.9 - 2.9] ng/mL	2.2

MV = Measured value

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

Date of Approval : 2019-04-15

Quality Control Manager :

S.LECOURT



ZYMUTEST PAI-1 Activity / PAI-1 Activité**REF** RK019A**Assay of tissue Plasminogen Activator Inhibitor Type I Activity PAI-1 by ELISA
/ Dosage ELISA du PAI-1 Actif**

For in vitro use only / Utilisation in vitro exclusivement - For research use only / Uniquement à usage de recherche

LOT F1801673

2021-11-22

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1900425 Concentration : 10 ng/mL (70 IU/mL) **
Control / Contrôle CI LOT : F1900367 Target value / Valeur cible : 6.9 ng/mL (48.3 IU/mL) ** Acceptance range / Domaine d'acceptation : [5.9 - 7.9] ng/mL (41.3 - 55.3 IU/mL) **
Control / Contrôle CII LOT : F1900368 Target value / Valeur cible : 2.4 ng/mL (16.8 IU/mL) ** Acceptance range / Domaine d'acceptation : : [1.9 - 2.9] ng/mL (13.3 - 20.3 IU/mL) **

(*) Standardization / Standardisation : **Calibrator and controls are related to international standard for PAI-1 from NIBSC (code: 92/654)**

** 1 ng equivalent to 7 IU

Note: Curve fitting suitable for RK019A 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 RK019A 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 : 2019-04-15

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT