



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. : F1901188**

**Expiration date : 2022-06-21**

Components	Quantity	Lot	Expiration Date
tPA pre-coated plate	12x8 wells	F1903068	2023-04-19
(h) PAI-1 standard	3 vials	F1903070	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	F1903122	2023-04-25
F-Sample diluent	2x50 ml	F1903028	2023-04-05
Wash solution	1x50 ml	F1900596	2022-10-25
Conjugate diluent	1x25 ml	F1900006	2022-06-21
TMB	1x25 ml	190405D01	2023-04-30
Sulfuric Acid 0,45M	1x6 ml	F1900172	2022-07-19

Analytical Data	Specification	Result
Reactivity	A450 for 8 ng/ml $\geq$ 1.00	2.04
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls in acceptance ranges
Blank	< 0.100	0.011
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	Acceptance Range	MV
OD	2.37	1.52	0.87	0.37	0.19	CI [ 5.6 - 7.6 ]	6.9
						CII [ 2.2 - 3.2 ]	2.8

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: 2019-11-26

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** F1901188

2022-06-21

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : <b>F1903070</b> Concentration : <b>10.3 ng/mL (***)</b>
Control / Contrôle CI LOT : <b>F1903061</b> Target value / Valeur cible : <b>6.6 ng/mL</b> Acceptance range / Domaine d'acceptation : <b>[ 5.6 - 7.6 ] ng/mL (***)</b>
Control / Contrôle CII LOT : <b>F1903063</b> Target value / Valeur cible : <b>2.7 ng/mL</b> Acceptance range / Domaine d'acceptation : <b>[ 2.2 – 3.2 ] ng/mL (***)</b>

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

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

(\*\*\*) Indicative information: 1 ng of PAI Activity equivalent to 7IU

Approved Date / Date d'Approbation : 2019-11-26

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT