



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. : F1801334**

**Expiration date : 2020-12-22**

Components	Quantity	Lot	Expiration Date
Anti-(h)-PAI-1 pre-coated plate	12x8 wells	F1801349	2022-03-14
(h) PAI-1 standard	3 vials	F1801350	2022-03-17
(h) PAI-1 Control I	1 vial	F1801351	2022-03-17
(h) PAI-1 Control II	1 vial	F1801352	2022-03-17
Anti-(h)-PAI-1 HRP immunoconjugate	3 vials	F1801364	2022-03-21
F-Sample diluent	2x50 ml	F1700770	2020-12-22
Wash solution	1x50 ml	F1800925	2021-11-22
Conjugate diluent	1x25 ml	F1700906	2021-01-27
TMB	1x25 ml	161208D01	2020-12-31
Sulfuric Acid 0,45M	1x6 ml	F1800049	2021-06-29

Analytical Data	Specification	Result
Reactivity	A450 for 8 ng/ml $\geq$ 1.40	1,79
Calibration Curve and Accuracy	Controls Measured Values within acceptance ranges	Controls within acceptance ranges
Blank	< 0.100	0.074
Detection threshold	$\leq$ 0.5 ng/ml	< 0.2 ng/ml

### Calibration Curve for information

						Acceptance Range	MV
Conc.	C	C/2	C/4	C/10	C/20	CI [ 31 - 43 ]	39
OD	1.997	1.258	0.715	0.300	0.218	CII [ 13 - 19 ]	15

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 : 19/10/2018

Quality Control Manager : A.M.VISSAC 



## 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** F1801334



2020-12-22

<u>Values assigned / Valeurs cibles (*)</u>
<b>Calibrator / Calibrateur LOT : F1801350</b> Concentration : <b>9.9 ng/mL</b>
<b>Control / Contrôle CI LOT : F1801351</b> Target value / Valeur cible : <b>37 ng/mL</b> Acceptance range / Domaine d'acceptation : <b>[ 31 - 43 ] ng/mL</b>
<b>Control / Contrôle CII LOT : F1801352</b> Target value / Valeur cible : <b>16 ng/mL</b> Acceptance range / Domaine d'acceptation : <b>[ 13 - 19 ] ng/mL</b>

(\*) Standardization / Standardisation : **N/A**

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 : 2018-10-19

Quality Control Manager / Responsable Contrôle Qualité : A.M.VISSAC