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CERTIFICATE OF ANALYSIS

**ZYMUTEST
PAI-1 Activity**

#RK019A

Lot : F1700774

Expiration date : 2020-04-08

905

ANALYSIS CERTIFICATE

PAI-1 Activity Elisa Kit

Lot : F1700774

CQ Release : 2017-08-29

Expiration date : 2020-04-08

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
tPA pre-coated plate	12x8 wells	42	F1700869	2021-01-12
PAI-1 activity Calibrator	3 vials	42	F1700898	2021-01-18
Anti-(h)-PAI-1-HRP immunoconjugate	3 vials	42	F1700903	2021-01-22
F-Sample diluent	2x50	42	F1700584	2020-11-02
Wash solution	1x50	42	F1700339	2020-09-22
Conjugate diluent	1x25	42	F1601097	2020-04-08
PAI-1 Control I	1 vial	42	F1700900	2021-01-18
PAI-1 Control II	1 vial	42	F1700901	2021-01-18
TMB substrate	1x25		160816D01	2020-08-30
Sulfuric Acid 0,45M	1x6	42	F1700445	2020-10-06

SNB

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Analytical data	Specifications
1. <u>Reactivity</u>	
A450 for calibrator 8 ng/ml : 1,636	≥ 1.00

2. <u>Plasma Standard</u>	
Concentration	10,8 ng/ml
	75,6 IU/ml *
CV	1,4 %
	8-12 ng/ml
	<i>Indicative</i>
	≤ 10 %

* 1 ng equivalent to 7 IU (established against WHO International Standard from NIBSC)

3. <u>Blank value</u>	
A450 for sample diluent :	0,0095
SD :	0,005
	< 0.100
	< 0.015

4. <u>Calibration curve</u>				N ≥ 10	
Curve fitting :		Polynomial 3			
Conc (ng/mL)	OD	SD	CV (%)	N	CV (%)
10,8	2,006	0,06	2,8	12	<10
5,4	1,194	0,03	2,8	12	<10
2,7	0,643	0,02	3,5	12	<10
1,08	0,257	0,008	3,2	12	<10
0,54	0,131	0,011	8,4	11	<10
0	0,009	0,005	/	12	

5. <u>Detection threshold</u>	
Concentration	
<0,5 ng/ml	≤ 0.5 ng/ml

6. <u>Controls</u>			
	Target value ng/ml	Measured value ng/ml	Acceptancy range ng/ml
PAI-1 Act. Control I	7,6	7,1	6,5 - 8,7
PAI-1 Act. Control II	2,0	1,9	1,6 - 2,4

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 2017-08-29
 2/2

QC Manager :



S. LECOURT
 F820-11/ZY/019A-v10



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 F1700774



2020-04-08

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1700898 Concentration : 10.8 ng/mL
Control / Contrôle CI LOT : F1700900 Target value / Valeur cible : 7.6 ng/mL Acceptance range / Domaine d'acceptation : [6.5 – 8.7] ng/mL
Control / Contrôle CII LOT : F1700901 Target value / Valeur cible : 2.0 ng/mL Acceptance range / Domaine d'acceptation : [1.6 – 2.4] ng/mL

(*) Standardization / Standardisation : Calibrator and controls are qualified against internal standard itself qualified against 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

Approved Date / Date d'Approbation : 2017-08-29

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT