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CERTIFICATE OF ANALYSIS

**ZYMUTEST
PAI-1 Activity**

#RK019A

Lot : F1601174

Expiration date : 2019-03-14

FLB

ANALYSIS CERTIFICATE

PAI-1 Activity Elisa Kit

Lot : F1601174

CQ Release : 2016-11-21

Expiration date : 2019-03-14

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
tPA pre-coated plate	12x8 wells	42	F1601017	2020-03-23
PAI-1 activity Calibrator	3 vials	42	F1600724	2019-12-30
Anti-(h)-PAI-1-HRP immunoconjugate	3 vials	42	F1600729	2020-03-27
F-Sample diluent	2x50	42	F1600737	2020-01-14
Wash solution	1x50	42	F1600780	2020-01-21
Conjugate diluent	1x25	42	150914G	2019-03
PAI-1 Control I	1 vial	42	F1601055	2020-03-30
PAI-1 Control II	1 vial	42	F1601056	2020-03-30
TMB substrate	1x25		150915D02	2019-09-30
Sulfuric Acid 0,45M	1x6	42	F1600740	2019-12-17



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Analytical data	Specifications				
1. <u>Reactivity</u>					
A450 for calibrator 8 ng/ml : 1,713	≥ 1.00				
2. <u>Plasma Standard</u>					
Concentration 11,2 ng/ml	8-12 ng/ml				
78,4 IU/ml *	<i>Indicative</i>				
CV 5,4 %	≤ 10 %				
* 1 ng equivalent to 7 IU (established against WHO International Standard from NIBSC)					
3. <u>Blank value</u>					
A450 for sample diluent : 0,006	< 0.100				
SD : 0,001	< 0.015				
4. <u>Calibration curve</u>					
Curve fitting : Polynom 3				N ≥ 10	
Conc (ng/mL)	OD	SD	CV (%)	N	CV (%)
11,2	2,127	0,051	2,4	10	<10
5,6	1,263	0,061	4,8	10	<10
2,8	0,644	0,053	8,3	10	<10
1,12	0,267	0,025	9,5	10	<10
0,56	0,142	0,010	7,2	10	<10
0	0,006	0,001	/	12	
5. <u>Detection threshold</u>		Concentration			
		<0,1 ng/ml		≤ 0.5 ng/ml	
6. <u>Controls</u>		Target value	Measured value	Acceptancy range	
	ng/ml	ng/ml	ng/ml		
PAI-1 Act. Control I	12,1	11,8	10,3 - 13,9		
PAI-1 Act. Control II	3,4	3,7	2,7 - 4,1		

Comments :	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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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 F1601174



2019-03-14

<u>Values assigned / Valeurs cibles (*)</u>
Calibrator / Calibrateur LOT : F1600724 Concentration : 11.2 ng/mL
Control / Contrôle CI LOT : F1601055 Target value / Valeur cible : 12.1 ng/mL Acceptance range / Domaine d'acceptation : [10.3 – 13.9] ng/mL
Control / Contrôle CII LOT : F1601056 Target value / Valeur cible : 3.4 ng/mL Acceptance range / Domaine d'acceptation : [2.7 – 4.1] 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 : 2016-11-21

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT