

ANALYSIS CERTIFICATE

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CERTIFICATE OF ANALYSIS

**ZYMUTEST
PAI-1 Activity**

#RK019A

Lot : 141211E

Expiration date : 2018-01



ANALYSIS CERTIFICATE

PAI-1 Activity Elisa Kit

Lot : 141211E

CQ Release : 07/01/2015

Expiration date : 2018-01

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
tPA pre-coated plate	12x8 wells	42	141112D	2018-05
PAI-1 activity Calibrator	3 vials	42	141030E	2018-04
Anti-(h)-PAI-1-HRP immunoconjugate	3 vials	42	141117E	2018-05
F-Sample diluent	2x50	42	141118C	2018-05
Wash solution	1x50	42	140701J	2018-01
Conjugate diluent	1x25	42	140929I	2018-03
PAI-1 Control I	1 vial	42	141121F	2018-05
PAI-1 Control II	1 vial	42	141121G	2018-05
TMB substrate	1x25		140817	2018-08
Sulfuric Acid 0,45M	1x6	42	141104C	2018-05



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PAI-1 Activity Elisa Kit

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Analytical data				Specifications	
1. <u>Reactivity</u>					
A450 for standard 10 ng/ml :		1,42		> 1.60	
2. <u>Plasma Standard</u>					
Concentration		11,7 ng/ml		9-15 ng/ml	
		81,9 IU/ml *		<i>Indicative</i>	
CV		3 %		≤ 10 %	
<small>* 1 ng equivalent to 7 IU (established against WHO International Standard from NIBSC)</small>					
3. <u>Blank value</u>					
A450 for sample diluent :		0,003		< 0.100	
SD :		0,002		< 0.015	
4. <u>Calibration curve</u>					
Conc.	OD	SD	CV (%)	N	CV (%)
11,7	1,625	0,07	4,5	N = 8	<10
5,85	0,913	0,09	9,3	N = 8	<10
2,93	0,486	0,04	8,3	N = 8	<10
1,17	0,203	0,02	8,5	N = 8	<10
0,59	0,108	0,01	9,7	N = 8	<10
0	0,003	0,002	/	N = 8	<10
5. <u>Detection limit</u>					
Sensitivity		Concentration <0,1 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	9,5	9,7		8,1 - 10,9	
PAI-1 Act. Control II	4,0	3,3		3,2 - 4,8	

<p>Comments : Accepted under waiver NCI1019</p>	<input checked="" type="checkbox"/> PASSED IN COMPLIANCE
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Date : 07/01/2015

QC Manager :

A.M.VISSAC



ZYMUTEST PAI-1 Activity

Référence RK019A

Dosage du PAI-1 actif

Utilisation *in vitro* exclusivement

Uniquement à usage de recherche

ZYMUTEST PAI-1 Activity

RK019A

Tissue- Plasminogen Activator Inhibitor Type I Activity

For *in vitro* use only

For research use only

FRANÇAIS

Lot : 141211E– Exp. : 2018-01

Calibrator

Lot : 141030E

Taux de PAI-1 actif :

11.7 ng/ml

81.9 IU/ml*

* Indicative equivalency established against WHO International Standard from NIBSC

Plasma Control I

Lot :141121F

Taux de PAI-1 actif :

9.5 ng/ml

Intervalle de confiance :

8.1 – 10.9 ng/ml

NE
13/11/15
[Signature]

Plasma Control II

Lot : 141121G

Taux de PAI-1 actif :

4.0 ng/ml

Intervalle de confiance :

3.2 – 4.8 ng/ml

ENGLISH

Lot : 141211E– Exp. : 2018-01

Calibrator

Lot : 141030E

PAI-1 activity concentration:

11.7 ng/ml

81.9 IU/ml*

* Indicative equivalency established against WHO International Standard from NIBSC

Plasma Control I

Lot :141121F

PAI-1 activity concentration:

9.5 ng/ml

Acceptance range:

8.1 -10.9 ng/ml

Plasma Control II

Lot : 141121G

PAI-1 activity concentration:

4.0 ng/ml

Acceptance range:

3.2 – 4.8 ng/ml