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# CERTIFICATE OF ANALYSIS



**ZYMUTEST  
(h) PAI-1 Antigen**

**#RK012A**

**Lot : 151030J**

**Expiration date :**

**2019-03**

503

## ANALYSIS CERTIFICATE

**(h) PAI 1 Ag Elisa Kit**

**Lot : 151030J**

**CQ Release : 02/11/2015**

**Expiration date : 2019-03**

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) PAI 1 pre-coated plate	12X8 wells	42	151013E	2019-04
(h) PAI 1 Standard	3 vials	42	151013J	2019-04
Anti-(h)-PAI 1-HRP immunoconjugate	3 vials	42	151015B	2019-04
F-Sample Diluent	2x50	42	151007B	2019-04
Wash Solution	1x50	42	151026C	2019-04
Conjugate Diluent	1x25	42	150914G	2019-03
Plasma PAI 1 Control I	1 vial	42	151013K	2019-04
Plasma PAI 1 Control II	1 vial	42	151013L	2019-04
TMB substrate	1x25		150914	2019-05
Sulfuric Acid 0,45M	1x6	42	151019B	2019-04

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**(h) PAI 1 Ag Elisa Kit**

**Lot : 151030J**

**CQ Release : 02/11/2015**

**Expiration date : 2019-03**

Analytical data	Specifications
<b>1. <u>Reactivity</u></b>	
A450 for standard at 8 ng/ml : <span style="float: right;">1,58</span>	≥ 1.40

<b>2. <u>PAI1 Ag Standard</u></b>	
Concentration: <span style="float: right;">10,7</span>	8,0-12,0 ng/ml
CV : <span style="float: right;">4,4</span>	≤ 10%
Standardization : <span style="float: right;">N/A</span>	

<b>3. <u>Blank value</u></b>	
A450 for sample diluent : <span style="float: right;">0,008</span>	< 0.100
SD : <span style="float: right;">0,003</span>	< 0.015

<b>4. <u>Calibration curve</u></b>					
Curve Fitting : <span style="float: right;">Polynomial 2</span>					
Elisa Software : <span style="float: right;">Magellan V.7.1 Tecan<sup>®</sup></span>					
Conc.	OD	SD	CV (%)	N	CV (%)
10,7 ng/ml	1,819	0,06	3,1	N = 10	<10
5,35 ng/ml	1,120	0,03	3,0	N = 10	<10
2,68 ng/ml	0,642	0,04	5,7	N = 10	<10
1,07 ng/ml	0,278	0,02	5,9	N = 10	<10
0,54 ng/ml	0,151	0,008	5,2	N = 10	<10
0 ng/ml	0,008	0,003	/	N = 10	<10

<b>5. <u>Detection threshold</u></b>	Concentration ng/ml	
	<0,1	≤ 0.5 ng/ml

<b>6. <u>Controls</u></b>	Target value ng/ml	Measured value ng/ml	Acceptance range
Control I	39	37	33 to 45 ng/ml
Control II	17	17	14 to 20 ng/ml

<b>Comments :</b>	<input checked="" type="checkbox"/> <b>PASSED IN COMPLIANCE</b>
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**Date : 02/11/2015**

**QC Manager :**

**S.LECOURT**



**ZYMUTEST PAI-1 Antigen**

Référence RK012A

PAI-1 Antigène

In vitro exclusivement

**ZYMUTEST PAI-1 Antigen**

# RK012A

PAI-1 Antigen

For in vitro use only

FRANÇAIS

ENGLISH

**Lot : 151030J – Exp. : 2019-03**

**Lot : 151030J – Exp. : 2019-03**

Standard PAI-1:Ag Lot : 151013J  
Taux de PAI-1:Ag: 10.7 ng/ml

Standard PAI-1:Ag Lot : 151013J  
PAI-1:Ag concentration: 10.7 ng/ml

Plasma Control I Lot : 151013K  
Taux de PAI-1:Ag: 39 ng/ml  
Intervalle de confiance : 33 - 45 ng/ml

Plasma Control I Lot : 151013K  
PAI-1:Ag concentration: 39 ng/ml  
Acceptance range: 33 - 45 ng/ml

Plasma Control II Lot : 151013L  
Taux de PAI-1:Ag: 17 ng/ml  
Intervalle de confiance : 14 – 20 ng/ml

Plasma Control II Lot : 151013L  
PAI-1:Ag concentration: 17 ng/ml  
Acceptance range: 14 – 20 ng/ml

*Dynamis*  
*22.11.15*