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[www.hyphen-biomed.com](http://www.hyphen-biomed.com)

# **CERTIFICATE OF ANALYSIS**

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

**#RK012A**

**Lot : F1700417      Expiration date : 2019-09-30**



## ANALYSIS CERTIFICATE

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

**Lot : F1700417**

**CQ Release : 2017-06-22**

**Expiration date : 2019-09-30**

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) PAI 1 pre-coated plate	12X8 wells	42	F1700610	2020-11-09
(h) PAI 1 Standard	3 vials	42	F1700503	2020-10-14
Anti-(h)-PAI 1-HRP immunoconjugate	3 vials	42	F1700611	2020-11-13
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
Plasma PAI 1 Control I	1 vial	42	F1601055	2020-03-30
Plasma PAI 1 Control II	1 vial	42	F1601056	2020-03-30
TMB substrate	1x25		150915D02	2019-09-30
Sulfuric Acid 0,45M	1x6	42	F1600893	2020-02-19

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Analytical data	Specifications																																										
<b>1. <u>Reactivity</u></b>																																											
A450 for standard at 8 ng/ml : <span style="float: right;"><b>1,657</b></span>	≥ 1.40																																										
<b>2. <u>PAI1 Ag Standard</u></b>																																											
Concentration: <span style="float: right;"><b>9,8</b></span> CV : <span style="float: right;"><b>1,2</b></span>	8,0-12,0 ng/ml ≤ 10%																																										
<b>3. <u>Blank value</u></b>																																											
A450 for sample diluent : <span style="float: right;"><b>0,0004</b></span> SD : <span style="float: right;"><b>0,003</b></span>	< 0.100 < 0.015																																										
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<b>Curve Fitting : Polynom 2</b>																																											
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**Date : 2107-06-22**

**QC Manager :**

**S. LECOURT**





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ENGLISH / FRANÇAIS



## 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** F1700417



2019-09-30

<u>Values assigned / Valeurs cibles (*)</u>
<b>Calibrator / Calibrateur</b> LOT : F1700503 Concentration : 9.8 ng/mL
<b>Control / Contrôle CI</b> LOT : F1601055 Target value / Valeur cible : 44 ng/mL Acceptance range / Domaine d'acceptation : [37-51] ng/mL
<b>Control / Contrôle CII</b> LOT : F1601056 Target value / Valeur cible : 16 ng/mL Acceptance range / Domaine d'acceptation : [13-19] ng/mL

(\*) Standardization / Standardisation : NA

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 : 2017-06-22

Quality Control Manager / Responsable Contrôle Qualité : S. LECOURT