

ANALYSIS CERTIFICATE

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CERTIFICATE OF ANALYSIS

**ZYMUTEST
tPA Ag ELISA kit**

#RK011A

Lot : F1700405 Expiration date : 2018-12-21



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tPA Ag ELISA kit

Lot : F1700405

QC Release : 2017-05-03

Expiration date : 2018-12-21

Components	Volume (mL)	Exp. (months)	Lot #	Exp. date
Anti (h) tPA pre-coated plate	12x8 wells	30	F1600739	2018-12-21
tPA standard 0	1 vial	42	F1700347	2020-09-17
tPA standard 1	1 vial	42	F1600720	2019-12-19
tPA standard 2	1 vial	42	F1600722	2019-12-09
tPA standard 3	1 vial	42	F1600723	2019-12-19
Anti-(h)-tPA-HRP immunoconjugate	3 vials	30	F1600721	2019-01-04
F-Sample diluent	2x50	42	151007B	2019-04
Wash solution	1x50	42	F1700339	2020-09-22
Conjugate diluent	1x25	42	F1601097	2020-04-08
Plasma Control I	1 vial	42	F1700434	2020-10-01
Plasma Control II	1 vial	42	F1700435	2020-10-01
TMB substrate	1x25		150915D02	2019-09-30
Sulfuric Acid 0,45M	1x6	42	F1600893	2020-02-19

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Analytical data	Specifications
1. <u>Reactivity</u>	
A450 for standard at 19 ng/mL : 1,730	≥ 1,40
2. <u>Plasma Standard 0</u>	
Concentration 0 ng/ml	0 ng/ml*
<u>Plasma Standard 1</u>	
Concentration 8 ng/ml	6-9 ng/ml*
CV 8,6 %	≤ 10 %
<u>Plasma Standard 2</u>	
Concentration 15 ng/ml	13-18 ng/ml*
CV 5,6 %	≤ 10 %
<u>Plasma Standard 3</u>	
Concentration 23 ng/ml	19-27 ng/ml*
CV 5,8 %	≤ 10 %
3. <u>Blank value</u>	
A450 for sample diluent : 0,014	< 0.100
SD : 0,003	< 0.015
4. <u>Calibration curve</u>	
Curve Fitting : poly2	
Conc.	OD
23 ng/ml	1,925
15 ng/ml	1,506
8 ng/ml	0,852
0 ng/ml	0,082
SD	CV (%)
0,06	3,1
0,07	4,3
0,03	4,0
0,005	/
N	CV (%)
N = 10	≤ 10
N = 10	≤ 10
N = 10	≤ 10
N = 10	≤ 10
5. <u>Detection threshold</u>	
Concentration	
<0,1	≤ 0.5 ng/ml
6. <u>Controls</u>	
Target value	Measured value
ng/ml	ng/ml
Control I	11,5
Control II	3,1
10,6	3,3
Acceptancy range	
9,8 to 13,2ng/ml	
2,5 to 3,7 ng/ml	

* Indicative Rate

Comments :



PASSED IN COMPLIANCE

Date : 2017-05-03

QC Manager : S.LECOURT



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ENGLISH / FRANÇAIS



Zymutest tPA Antigen / tPA Antigène

REF RK011A

Assay of tPA Antigen by ELISA / Dosage ELISA du tPA Antigène

For in vitro use only / Utilisation in vitro exclusivement

LOT F1700405

 2018-12-21

<u>Values assigned / Valeurs cibles (*)</u>
Standard Plasma / Plasma Standard 0 LOT : F1700347 Concentration : 0 ng/mL
Standard Plasma / Plasma Standard 1 LOT : F1600720 Concentration : 8 ng/mL
Standard Plasma / Plasma Standard 2 LOT : F1600722 Concentration : 15 ng/mL
Standard Plasma / Plasma Standard 3 LOT : F1600723 Concentration : 23 ng/mL
Control / Contrôle CI LOT : F1700434 Target value / Valeur cible : 11.5 ng/mL Acceptance range / Domaine d'acceptation : [9.8 – 13.2] ng/mL
Control / Contrôle CII LOT : F1700435 Target value / Valeur cible : 3.1 ng/mL Acceptance range / Domaine d'acceptation : [2.5 – 3.7] ng/mL

(*) Standardization / Standardisation : Calibrator and controls are related to International Standard from NIBSC 94/730

Note: Curve fitting suitable for RK011A using Magellan software (Tecan ©) : second-degree polynomial (**), third-degree polynomial (**), 4 parameters, 4 parameters marquardt, 5 parameters marquardt, akima, and point to point / Les modes d'interpolation adaptés pour RK011A sur le logiciel Magellan (Tecan ©) sont : polynôme de degré 2 (**), polynôme de degré 3 (**), 4 paramètres, 4 paramètres marquardt, 5 paramètres marquardt, akima, et point par point.

(**) Best fit suggested / Mode d'interpolation à favoriser

Approved Date / Date d'Approbation : 2017-05-03

Quality Control Manager / Responsable Contrôle Qualité : S.LECOURT